

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).

Staging AJCC Edition 8, Breast CDISC Aligned NCI Standard Template Module Definitions

Mapping to the CDASH:

N/A

Mapping to the SDTM:

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

- RS – Disease Response and Clin Classification (v3.3)

Staging AJCC Edition 8, Breast 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
TNM Staging System Assessment Date (m) 7110971 QSTMNDT	The date the TNM staging was completed represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: No Match; SDTM: No Match	DATE
Breast Cancer AJCC Edition 8 Clinical Tumor T Category (c) 7095155 AJBR201C	Extent of the primary breast carcinoma based on information obtained from the date of cancer diagnosis until the start of definitive treatment, or within four months (whichever is shorter), using AJCC Ed. 8 criteria. CDASH: No Match; SDTM: RSORRES (6642369) = value of AJBR201C, RSSTRESC (6642356) = value of AJBR201C, RSTESTCD (6620609) = "AJCC201", RSTEST (6620604) = "AJCC2-Primary Tumor (T)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "BREAST CANCER CLINICAL"; Conditionality Rule: Inclusion based on patient population being studied.	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Breast Cancer AJCC Edition 8 Clinical Regional Lymph Node N Category (c) 7095180 AJBR202C	Extent of the regional lymph node involvement for breast carcinoma based on information obtained from the date of cancer diagnosis until the start of definitive treatment, or within four months (whichever is shorter), using AJCC Ed. 8 criteria. CDASH: No Match; SDTM: RSORRES (6642369) = value of AJBR202C, RSSTRESC (6642356) = value of AJBR202C, RSTESTCD (6620609) = "AJCC202", RSTEST (6620604) = "AJCC2- Regional Lymph Nodes (N)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "BREAST CANCER CLINICAL"; Conditionality Rule: Inclusion based on patient population being studied.	CHARACTER. Use choice list.
Breast Cancer AJCC Edition 8 Clinical Distant Metastasis M Category (c) 7095121 AJBR203C	Extent of the distant metastasis for breast carcinoma based on information obtained from the date of cancer diagnosis until the start of definitive treatment, or within four months (whichever is shorter), using AJCC Ed. 8 criteria. CDASH: No Match; SDTM: RSORRES (6642369) = value of AJBR203C, RSSTRESC (6642356) = value of AJBR203C, RSTESTCD (6620609) = "AJCC203", RSTEST (6620604) = "AJCC2- Distant Metastasis (M)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "BREAST CANCER CLINICAL"; Conditionality Rule: Inclusion based on patient population being studied.	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Breast Cancer AJCC Edition 8 Clinical Prognostic Group Stage (c) 7093937 AJBR204C	<p>Clinical stage group for breast carcinoma based on the combined evaluation of T, N, and M categories that should be used in countries where HER2, ER, and PR biomarker tests are routinely performed for patient care (US, Canada, etc.), using AJCC Ed. 8 criteria.</p> <p>CDASH: No Match; SDTM: RSORRES (6642369) = value of AJBR204C, RSSTRESC (6642356) = value of AJBR204C, RSTESTCD (6620609) = "AJCC204, RSTEST (6620604) = "AJCC2-Anatomic Stage", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "BREAST CANCER CLINICAL"; Conditionality Rule: Inclusion based on patient population being studied.</p>	CHARACTER. Use choice list.
Breast Cancer AJCC Edition 8 Pathologic Tumor T Category (c) 7093780 AJBR201P	<p>Extent of the primary breast carcinoma based on clinical stage information combined with operative findings, and evidence obtained from pathology review when surgery is the first definitive therapy, using AJCC Ed. 8 criteria.</p> <p>CDASH: No Match; SDTM: RSORRES (6642369) = value of AJBR201P, RSSTRESC (6642356) = value of AJBR201P, RSTESTCD (6620609) = "AJCC201", RSTEST (6620604) = "AJCC2-Primary Tumor (T)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "BREAST CANCER PATHOLOGIC"; Conditionality Rule: Inclusion based on patient population being studied.</p>	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Breast Cancer AJCC Edition 8 Pathologic Regional Lymph Node N Category (c) 7093765 AJBR202P	Extent of the regional lymph node involvement for breast carcinoma based on clinical stage information combined with operative findings, and evidence obtained from pathology review when surgery is the first definitive therapy, using AJCC Ed. 8 criteria. CDASH: No Match; SDTM: RSORRES (6642369) = value of AJBR202P, RSSTRESC (6642356) = value of AJBR202P, RSTESTCD (6620609) = "AJCC202", RSTEST (6620604) = "AJCC2- Regional Lymph Nodes (N)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "BREAST CANCER PATHOLOGIC"; Conditionality Rule: Inclusion based on patient population being studied.	CHARACTER. Use choice list.
Breast Cancer AJCC Edition 8 Pathologic Distant Metastasis M Category (c) 7093927 AJBR203P	Extent of the distant metastasis for breast carcinoma based on clinical stage information combined with operative findings, and evidence obtained from pathology review when surgery is the first definitive therapy, using AJCC Ed. 8 criteria. CDASH: No Match; SDTM: RSORRES (6642369) = value of AJBR203P, RSSTRESC (6642356) = value of AJBR203P, RSTESTCD (6620609) = "AJCC203", RSTEST (6620604) = "AJCC2- Distant Metastasis (M)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "BREAST CANCER PATHOLOGIC"; Conditionality Rule: Inclusion based on patient population being studied.	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Breast Cancer AJCC Edition 8 Pathologic Prognostic Group Stage (c) 7092961 AJBR204P	<p>Pathologic stage group for breast carcinoma based on the combined evaluation of T, N, and M categories that should be used in countries where HER2, ER, and PR biomarker tests are routinely performed for patient care (US, Canada, etc.), using AJCC Ed. 8 criteria.</p> <p>CDASH: No Match; SDTM: RSORRES (6642369) = value of AJBR204P, RSSTRESC (6642356) = value of AJBR204P, RSTESTCD (6620609) = "AJCC204", RSTEST (6620604) = "AJCC2-Anatomic Stage", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "BREAST CANCER PATHOLOGIC"; Conditionality Rule: Inclusion based on patient population being studied.</p>	CHARACTER. Use choice list.
TNM Staging System Assessment Timepoint Type (o) 7110980 QSTMNTYP	<p>The type of TNM staging completed based on their occurrence at a point in time.</p> <p>CDASH: No Match; SDTM: No Match</p>	CHARACTER. Use choice list.

Annotated CRF: Staging AJCC Edition 8, Breast 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: Staging AJCC Edition 8, Breast CDISC Aligned NCI
Standard Template

Mandatory Questions

CRF Question	Value Domain
Date Current Staging Assessment Completed (7110971) CDE Short Name: QSTMNDT <div style="border: 1px solid blue; padding: 2px; width: fit-content;">CDASH: No Match</div> <div style="border: 1px solid red; padding: 2px; width: fit-content;">SDTM: No Match</div>	DATE – Maximum Length = 11

Conditional Questions

CRF Question	Value Domain
<p>Clinical T category (7095155) CDE Short Name: AJBR201C</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: RSORRES (6642369) = value of AJBR201C, RSSTRESC (6642356) = value of AJBR201C, RSTESTCD (6620609) = "AJCC201", RSTEST (6620604) = "AJCC2-Primary Tumor (T)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "BREAST CANCER CLINICAL"</p> </div>	<p>CHARACTER – Maximum Length = 13</p> <ul style="list-style-type: none"> <input type="checkbox"/> T0 – Breast Cancer pT0 TNM Finding v8 <input type="checkbox"/> T1 – Breast Cancer pT1 TNM Finding v8 <input type="checkbox"/> T1a – Breast Cancer pT1a TNM Finding v8 <input type="checkbox"/> T1b – Breast Cancer pT1b TNM Finding v8 <input type="checkbox"/> T1c – Breast Cancer pT1c TNM Finding v8 <input type="checkbox"/> T1mi – Breast Cancer pT1mi TNM Finding v8 <input type="checkbox"/> T2 – Breast Cancer pT2 TNM Finding v8 <input type="checkbox"/> T3 – Breast Cancer pT3 TNM Finding v8 <input type="checkbox"/> T4 – Breast Cancer pT4 TNM Finding v8 <input type="checkbox"/> T4a – Breast Cancer pT4a TNM Finding v8 <input type="checkbox"/> T4b – Breast Cancer pT4b TNM Finding v8 <input type="checkbox"/> T4c – Breast Cancer pT4c TNM Finding v8 <input type="checkbox"/> T4d – Breast Cancer pT4d TNM Finding v8 <input type="checkbox"/> Tis (DCIS) – Breast Cancer pTis (DCIS) TNM Finding v8 <input type="checkbox"/> Tis (Paget) – Breast Cancer pTis (Paget) TNM Finding v8 <input type="checkbox"/> TX – Breast Cancer pTX TNM Finding v8

CRF Question	Value Domain
<p>Clinical N category (7095180) CDE Short Name: AJBR202C</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: RSORRES (6642369) = value of AJBR202C, RSSTRESC (6642356) = value of AJBR202C, RSTESTCD (6620609) = "AJCC202", RSTEST (6620604) = "AJCC2-Regional Lymph Nodes (N)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "BREAST CANCER CLINICAL"</p> </div>	<p>CHARACTER – Maximum Length = 5</p> <ul style="list-style-type: none"> <input type="checkbox"/> cN0 – Breast Cancer cN0 TNM Finding v8 <input type="checkbox"/> cN1 – Breast Cancer cN1 TNM Finding v8 <input type="checkbox"/> cN1mi – Breast Cancer cN1mi TNM Finding v8 <input type="checkbox"/> cN2 – Breast Cancer cN2 TNM Finding v8 <input type="checkbox"/> cN2a – Breast Cancer cN2a TNM Finding v8 <input type="checkbox"/> cN2b – Breast Cancer cN2b TNM Finding v8 <input type="checkbox"/> cN3 – Breast Cancer cN3 TNM Finding v8 <input type="checkbox"/> cN3a – Breast Cancer cN3a TNM Finding v8 <input type="checkbox"/> cN3b – Breast Cancer cN3b TNM Finding v8 <input type="checkbox"/> cN3c – Breast Cancer cN3c TNM Finding v8 <input type="checkbox"/> cNX – Breast Cancer cNX TNM Finding v8
<p>Clinical M category (7095121) CDE Short Name: AJBR203C</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: RSORRES (6642369) = value of AJBR203C, RSSTRESC (6642356) = value of AJBR203C, RSTESTCD (6620609) = "AJCC203", RSTEST (6620604) = "AJCC2-Distant Metastasis (M)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "BREAST CANCER CLINICAL"</p> </div>	<p>CHARACTER – Maximum Length = 7</p> <ul style="list-style-type: none"> <input type="checkbox"/> cM0 – Breast Cancer cM0 TNM Finding v8 <input type="checkbox"/> cM0(i+) – Breast Cancer cM0(i+) TNM Finding v8 <input type="checkbox"/> cM1 – Breast Cancer cM1 TNM Finding v8 <input type="checkbox"/> pM1 – Breast Cancer pM1 TNM Finding v8

CRF Question	Value Domain
<p data-bbox="240 205 651 237">Clinical disease stage (7093937)</p> <p data-bbox="240 243 605 275">CDE Short Name: AJBR204C</p> <div data-bbox="289 321 769 373" style="border: 1px solid blue; padding: 2px; margin: 10px 0;"> <p data-bbox="300 331 524 363">CDASH: No Match</p> </div> <div data-bbox="289 407 769 701" style="border: 1px solid red; padding: 2px; margin: 10px 0;"> <p data-bbox="300 420 747 688">CDASH: No Match; SDTM: RSORRES (6642369) = value of AJBR204C, RSSTRESC (6642356) = value of AJBR204C, RSTESTCD (6620609) = "AJCC204, RSTEST (6620604) = "AJCC2-Anatomic Stage", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "BREAST CANCER CLINICAL";</p> </div>	<p data-bbox="821 205 1268 237">CHARACTER – Maximum Length = 4</p> <ul style="list-style-type: none"> <li data-bbox="821 296 1321 359"><input type="checkbox"/> 0 – Prognostic Stage 0 Breast Cancer AJCC v8 <li data-bbox="821 369 1341 432"><input type="checkbox"/> IA – Prognostic Stage IA Breast Cancer AJCC v8 <li data-bbox="821 443 1341 506"><input type="checkbox"/> IB – Prognostic Stage IB Breast Cancer AJCC v8 <li data-bbox="821 516 1354 579"><input type="checkbox"/> IIA – Prognostic Stage IIA Breast Cancer AJCC v8 <li data-bbox="821 590 1354 653"><input type="checkbox"/> IIB – Prognostic Stage IIB Breast Cancer AJCC v8 <li data-bbox="821 663 1370 726"><input type="checkbox"/> IIIA – Prognostic Stage IIIA Breast Cancer AJCC v8 <li data-bbox="821 737 1370 800"><input type="checkbox"/> IIIB – Prognostic Stage IIIB Breast Cancer AJCC v8 <li data-bbox="821 810 1370 873"><input type="checkbox"/> IIIC – Prognostic Stage IIIC Breast Cancer AJCC v8 <li data-bbox="821 884 1341 947"><input type="checkbox"/> IV – Prognostic Stage IV Breast Cancer AJCC v8

CRF Question	Value Domain
<p>Pathologic T category (7093780) CDE Short Name: AJBR201P</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: RSORRES (6642369) = value of AJBR201P, RSSTRESC (6642356) = value of AJBR201P, RSTESTCD (6620609) = "AJCC201", RSTEST (6620604) = "AJCC2-Primary Tumor (T)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "BREAST CANCER PATHOLOGIC"</p> </div>	<p>CHARACTER – Maximum Length = 13</p> <ul style="list-style-type: none"> <input type="checkbox"/> T0 – Breast Cancer pT0 TNM Finding v8 <input type="checkbox"/> T1 – Breast Cancer pT1 TNM Finding v8 <input type="checkbox"/> T1a – Breast Cancer pT1a TNM Finding v8 <input type="checkbox"/> T1b – Breast Cancer pT1b TNM Finding v8 <input type="checkbox"/> T1c – Breast Cancer pT1c TNM Finding v8 <input type="checkbox"/> T1mi – Breast Cancer pT1mi TNM Finding v8 <input type="checkbox"/> T2 – Breast Cancer pT2 TNM Finding v8 <input type="checkbox"/> T3 – Breast Cancer pT3 TNM Finding v8 <input type="checkbox"/> T4 – Breast Cancer pT4 TNM Finding v8 <input type="checkbox"/> T4a – Breast Cancer pT4a TNM Finding v8 <input type="checkbox"/> T4b – Breast Cancer pT4b TNM Finding v8 <input type="checkbox"/> T4c – Breast Cancer pT4c TNM Finding v8 <input type="checkbox"/> T4d – Breast Cancer pT4d TNM Finding v8 <input type="checkbox"/> Tis (DCIS) – Breast Cancer pTis (DCIS) TNM Finding v8 <input type="checkbox"/> Tis (Paget) – Breast Cancer pTis (Paget) TNM Finding v8 <input type="checkbox"/> TX – Breast Cancer pTX TNM Finding v8

CRF Question	Value Domain
<p>Pathologic N category (7093765) CDE Short Name: AJBR202P</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: RSORRES (6642369) = value of AJBR202P, RSSTRESC (6642356) = value of AJBR202P, RSTESTCD (6620609) = "AJCC202", RSTEST (6620604) = "AJCC2-Regional Lymph Nodes (N)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "BREAST CANCER PATHOLOGIC"</p> </div>	<p>CHARACTER – Maximum Length = 9</p> <ul style="list-style-type: none"> <input type="checkbox"/> pN0 – Breast Cancer pN0 TNM Finding v8 <input type="checkbox"/> pN0(i+) – Breast Cancer pN0(i+) TNM Finding v8 <input type="checkbox"/> pN0(mol+) – Breast Cancer pN0(mol+) TNM Finding v8 <input type="checkbox"/> pN1 – Breast Cancer pN1 TNM Finding v8 <input type="checkbox"/> pN1a – Breast Cancer pN1a TNM Finding v8 <input type="checkbox"/> pN1b – Breast Cancer pN1b TNM Finding v8 <input type="checkbox"/> pN1c – Breast Cancer pN1c TNM Finding v8 <input type="checkbox"/> pN1m – iBreast Cancer pN1mi TNM Finding v8 <input type="checkbox"/> pN2 – Breast Cancer pN2 TNM Finding v8 <input type="checkbox"/> pN2a – Breast Cancer pN2a TNM Finding v8 <input type="checkbox"/> pN2b – Breast Cancer pN2b TNM Finding v8 <input type="checkbox"/> pN3 – Breast Cancer pN3 TNM Finding v8 <input type="checkbox"/> pN3a – Breast Cancer pN3a TNM Finding v8 <input type="checkbox"/> pN3b – Breast Cancer pN3b TNM Finding v8 <input type="checkbox"/> pN3c – Breast Cancer pN3c TNM Finding v8 <input type="checkbox"/> pNX – Breast Cancer pNX TNM Finding v8
<p>Pathologic M category (7093927) CDE Short Name: AJBR203P</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: RSORRES (6642369) = value of AJBR203P, RSSTRESC (6642356) = value of AJBR203P, RSTESTCD (6620609) = "AJCC203", RSTEST (6620604) = "AJCC2-Distant Metastasis (M)", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "BREAST CANCER PATHOLOGIC"</p> </div>	<p>CHARACTER – Maximum Length = 7</p> <ul style="list-style-type: none"> <input type="checkbox"/> cM0 – Breast Cancer cM0 TNM Finding v8 <input type="checkbox"/> cM0(i+) – Breast Cancer cM0(i+) TNM Finding v8 <input type="checkbox"/> cM1 – Breast Cancer cM1 TNM Finding v8 <input type="checkbox"/> pM1 – Breast Cancer pM1 TNM Finding v8

CRF Question	Value Domain
<p data-bbox="245 212 691 239">Pathologic disease stage (7092961)</p> <p data-bbox="245 247 602 275">CDE Short Name: AJBR204P</p> <div data-bbox="289 323 769 373" style="border: 1px solid blue; padding: 2px; margin: 10px 0;"> <p data-bbox="302 338 524 365">CDASH: No Match</p> </div> <div data-bbox="289 407 769 674" style="border: 1px solid red; padding: 2px; margin: 10px 0;"> <p data-bbox="302 422 748 659">SDTM: RSORRES (6642369) = value of AJBR204P, RSSTRESC (6642356) = value of AJBR204P, RSTESTCD (6620609) = "AJCC204", RSTEST (6620604) = "AJCC2-Anatomic Stage", RSCAT (6659633) = "AJCC V8", RSSCAT (No CDE) = "BREAST CANCER PATHOLOGIC"</p> </div>	<p data-bbox="824 212 1268 239">CHARACTER – Maximum Length = 4</p> <ul style="list-style-type: none"> <li data-bbox="824 296 1312 359"><input type="checkbox"/> 0– Prognostic Stage 0 Breast Cancer AJCC v8 <li data-bbox="824 369 1341 432"><input type="checkbox"/> IA – Prognostic Stage IA Breast Cancer AJCC v8 <li data-bbox="824 443 1341 506"><input type="checkbox"/> IB – Prognostic Stage IB Breast Cancer AJCC v8 <li data-bbox="824 516 1354 579"><input type="checkbox"/> IIA – Prognostic Stage IIA Breast Cancer AJCC v8 <li data-bbox="824 590 1354 653"><input type="checkbox"/> IIB – Prognostic Stage IIB Breast Cancer AJCC v8 <li data-bbox="824 663 1370 726"><input type="checkbox"/> IIIA – Prognostic Stage IIIA Breast Cancer AJCC v8 <li data-bbox="824 737 1370 800"><input type="checkbox"/> IIIB – Prognostic Stage IIIB Breast Cancer AJCC v8 <li data-bbox="824 810 1370 873"><input type="checkbox"/> IIIC – Prognostic Stage IIIC Breast Cancer AJCC v8 <li data-bbox="824 884 1341 947"><input type="checkbox"/> IV – Prognostic Stage IV Breast Cancer AJCC v8

Optional Questions

CRF Question	Value Domain
<p data-bbox="240 262 617 294">Staging Time Point (7110980)</p> <p data-bbox="240 300 621 331">CDE Short Name: QSTMNTYP</p> <div data-bbox="289 380 769 432" style="border: 1px solid blue; padding: 2px; margin: 10px 0;">CDASH: No Match</div> <div data-bbox="289 464 769 516" style="border: 1px solid red; padding: 2px; margin: 10px 0;">SDTM: No Match</div>	<p data-bbox="818 262 1284 294">CHARACTER – Maximum Length = 18</p> <ul style="list-style-type: none"><li data-bbox="818 348 1328 380"><input type="checkbox"/> Current Diagnosis – Current Diagnosis<li data-bbox="818 394 1263 426"><input type="checkbox"/> Initial Diagnosis – First Diagnosis<li data-bbox="818 441 1141 472"><input type="checkbox"/> Restaging – Restaging<li data-bbox="818 487 1263 539"><input type="checkbox"/> Study Enrollment – Clinical Study Enrollment