Clinical Data Form

Breast Carcinoma (BRCA)

The Clinical Data Form (CDF) should be completed for every case. This form can be completed at the time the samples are submitted, or after that date. Samples will not be sent for sequencing or characterization until all clinical data have been received by the BCR.

Spreadsheet Submissions

If a BCR-created spreadsheet is being completed in lieu of the electronic form(s) in OpenClinica, please reference this document to accurately map the information from the Tissue Source Site's (TSS) database to the spreadsheet. Each column in the spreadsheet represents a CDF, and a single form is needed for each case, regardless of the number of samples submitted for the case.

#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
1	N/A	TSS Patient Identifier		An identifier provided by the TSS that should be consistent with the Sample Submission Form (SSF).
2	5102355	Status of the protocol used to procure this sample at the time the sample was submitted for this project	☐ Recruiting ☐ Active; not recruiting ☐ Completed ☐ Suspended ☐ Terminated	Indicates the status of the protocol used to procure the submitted sample, at the time the sample was submitted for this project. **Recruiting**: Participants were still being recruited **Active**: Study ongoing, but participants were not being recruited **Completed**: Study concluded and patients were no longer being examined or treated **Suspended**: Recruiting and enrollment was halted prematurely but may resume **Terminated**: Recruiting and enrollment was halted prematurely and will not resume

Demographic Information

#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
3	2660030	Patient Sex	☐ Male ☐ Female ☐ Unknown	The biological sex of the patient.
4*	2896950 2896952 2896954	Date of Birth	Month: ___ ___ Day: ___ ___ Year: ___ ___ ___ ___	The date the patient was born.
5	2192199	Race *(check all that apply)*	☐ American Indian or Alaskan Native ☐ Asian ☐ White ☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander ☐ Not Reported ☐ Unknown	The patient's self-reported race. **American Indian or Alaska Native**: A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment. **Asian**: A person having origins in any of the original peoples of the Far East, Southeast Asia, or in the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. **White**: A person having origins in any of the original peoples of Europe, the Middle East, or North Africa. **Black or African American**: A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American." **Native Hawaiian or other Pacific Islander**: A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island.

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#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
6	2192217	Ethnicity	☐ Not Hispanic or Latino ☐ Hispanic or Latino ☐ Not Reported ☐ Unknown	The patient's self-described ethnicity. **Not Hispanic or Latino**: A person not meeting the definition of Hispanic or Latino. **Hispanic or Latino**: A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race.
7	649	Height at Diagnosis	(cm)	The patient's height in centimeters, at the time of diagnosis.
8	651	Weight at Diagnosis	(kg)	The patient's weight in kilograms, at the time of diagnosis.

Medical and Health Information

#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
9	3382736	Has the patient had any prior malignancies diagnosed?	☐ Yes ☐ No ☐ Unknown	If the patient had a malignancy diagnosed prior to or at the time the submitted sample was diagnosed, make sure this information was documented in the "Other Malignancy" section on the "Sample Submission Form" spreadsheet or form in OpenClinica.
10	3119700	If the patient had prior malignancies, did the patient receive systemic chemo or radio-therapy?	☐ Radiation ☐ Chemotherapy ☐ Other ☐ Unknown	Indicates whether the patient received radiation, chemotherapy or another type of treatment for a prior or synchronous malignancy.
11	2691192	Does the patient have a family history (first degree relatives only) of cancer?	☐ Yes ☐ No ☐ Unknown	Indicates whether any of the patient's first degree relatives (including parents, siblings and children) have a history of cancer.
12	2783641 3457764	If the patient has a family history of cancer, indicate the family member and type of cancer.	Family member / Site of cancer ☐ Mother ☐ Father ☐ Sister ☐ Brother ☐ Daughter ☐ Son	Provides detail regarding the patient's first degree family members who have had a history of cancer. *See the BCR spreadsheet or OpenClinica for a complete list of sites of cancer.*
13	2181650	Tobacco Smoking Status at the Time of Diagnosis	☐ Lifelong non-smoker ☐ Smoker at diagnosis ☐ Reformed smoker at diagnosis **for more than 15 years** ☐ Reformed smoker at diagnosis **for 15 years or less** ☐ Reformed smoker at diagnosis **duration unknown** ☐ Smoking history not documented	The patient's self-reported history of tobacco smoking. **Lifelong non-smoker**: Someone who has smoked <100 cigarettes during their lifetime. **Smoker at diagnosis**: Someone who was a daily or occasional smoker at diagnosis. **Reformed smoker**: Someone who was previously a daily or occasional smoker, but at the time of diagnosis was no longer smoking.
14	2228604	Tobacco Smoking Year of Onset		The year the patient began smoking.
15	2228610	Tobacco Smoking Year of Quitting		The year the patient stopped smoking.

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#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
16	2955385	Number of Pack Years Smoked		The patient's lifetime exposure, calculated with the following equation: **(# Cigarettes Smoked per Day)(Years Smoked) / 20** *The number of cigarettes smoked per day multiplied by the years smoked and divided by 20.*
17	88	Performance Status Scale: Eastern Cooperative Oncology Group (ECOG) at Time of Diagnosis	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5	The patient's functional performance at the time of diagnosis, based on the categories defined by the Eastern Cooperative Oncology Group (ECOG). **0** = Asymptomatic **1** = Symptomatic but fully ambulatory **2** = Symptomatic but in bed less than 50% of day **3** = Symptomatic, in bed more than 50% of the day, but not bed-ridden **4** = Bed ridden **5** = Dead
18	2003853	Performance Status Score: Karnofsky Score at Time of Diagnosis	☐ 100 ☐ 90 ☐ 80 ☐ 70 ☐ 60 ☐ 50 ☐ 40 ☐ 30 ☐ 20 ☐ 10 ☐ 0	The patient's functional capabilities at the time of diagnosis, based on the categories defined by the Karnofsky Score. **100** = Normal, no complaints; no evidence of disease **90** = Able to carry on normal activity; minor signs or symptoms of disease **80** = Normal activity with effort; some signs or symptoms of disease **70** = Cares for self; unable to carry on normal activity or to do active work **60** = Requires occasional assistance; but is able to care for most of his/her needs **50** = Requires considerable assistance and frequent medical care **40** = Disabled; requires special care **30** = Severely disabled **20** = Very sick; requiring hospitalization **10** = Moribund; fatal processes progressing rapidly **0** = Dead
19	2957270	Menopause Status at Time of Diagnosis	☐ Premenopausal ☐ Perimenopausal ☐ Postmenopausal ☐ Indeterminate or Unknown ☐ Not Evaluated	The patient's menopause status at the time the time of diagnosis.

Diagnostic/Pathologic Information

#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
20*	5102356 5102357 5102358	Date of Clinical Diagnosis	Month: ___ ___ Day: ___ ___ Year: ___ ___ ___ ___	The date the patient was first diagnosed with the primary malignancy, based on a clinical exam, scan, or pathologic review of a biopsy or surgical resection.
21	5102378	Method of Clinical Diagnosis	☐ Physical Exam ☐ Imaging (X-ray; Scan; Utrasound; etc.) ☐ Biochemical Evidence of Disease ☐ Cytology ☐ Other	The method used to clinically diagnose the primary malignancy.

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#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
22*	2896956 2896958 2896960	Date of Initial Pathologic Diagnosis of Primary Tumor	Month: ___ ___ Day: ___ ___ Year: ___ ___ ___ ___	The date the tumor that yielded the submitted sample was initially pathologically diagnosed.
23	2757941	Method of Initial Pathologic Diagnosis	☐ Lumpectomy ☐ Simple Mastectomy ☐ Modified Radical Mastectomy ☐ Biopsy (all types) ☐ Other Surgical Resection (Please Specify)	The procedure performed to procure the sample used for the initial pathologic diagnosis.
24	2757948	Other Method of Initial Pathologic Diagnosis		The procedure performed to procure the sample used for initial pathologic diagnosis not included in the provided list.
25	827	Laterality of Primary Malignancy	☐ Right ☐ Left	The laterality of the primary tumor that yielded the submitted sample.
26	3427536	Primary Site of Disease	☐ Breast	The anatomic site of the primary tumor that yielded the submitted sample.
27	3108203	Region of the Primary Malignancy in the Breast *(select all that apply)*	☐ Upper Inner Quadrant ☐ Upper Outer Quadrant ☐ Lower Inner Quadrant ☐ Lower Outer Quadrant	The region(s) of the breast where the primary tumor that yielded the submitted sample was located.
28	3081934	Histological Subtype	☐ Infiltrating Ductal Carcinoma ☐ Infiltrating Lobular Carcinoma ☐ Infiltrating Carcinoma NOS ☐ Mucinous Carcinoma ☐ Medullary Carcinoma ☐ Metaplastic Carcinoma ☐ Mixed Ductal and Lobular ☐ Mixed Histology (Please Specify) ☐ Other Histology (Please Specify)	The histologic diagnosis of the entire tumor that yielded the submitted sample, as determined at the date of initial pathologic diagnosis.
29	2584114	Other or Mixed Histologic Subtype		The specific histologic diagnosis not included in the provided list.
30	5457224	First Surgical Procedure	☐ Lumpectomy ☐ Simple Mastectomy ☐ Modified Radical Mastectomy ☐ Unknown ☐ Other (Please Specify)	The first surgical procedure performed to remove the tumor that yielded the submitted sample.
31	3020338	Other First Surgical Procedure		The first surgical procedure performed not included in the provided list.

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#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
32	3114007	Margin Status after First Surgical Procedure	☐ Positive (+) ☐ Negative (-) ☐ Close ☐ Unknown	The status of residual disease after the first surgical procedure was completed.
33	5457225	If the margins were positive after the first surgical procedure, what was the surgical method performed to achieve negative margins?	☐ Surgery Not Performed ☐ Lumpectomy ☐ Simple Mastectomy ☐ Modified Radical Mastectomy ☐ Unknown ☐ Other (Please Specify)	The second surgical resection performed when positive margins remained after the first surgery.
34	5457226	Other Surgical Method Performed to Achieve Negative Margins		The second surgical resection performed when positive margins remained after the first surgery, if it was not included in the provided list.
35	5457227	Margin Status after Second Surgical Procedure	☐ Positive (+) ☐ Negative (-) ☐ Close ☐ Unknown	The status of residual disease after the second surgical procedure was completed.
36	2516112	Axillary Staging Method	☐ No Axillary Staging ☐ Sentinel Lymph Node Biopsy Alone ☐ Sentinel Lymph Node Biopsy Plus Axillary Dissection ☐ Axillary Lymph Node Dissection Alone ☐ Unknown ☐ Other (Please Specify)	The method used to determine the staging of the axillary lymph node.
37	3124496	Other Method of Axillary Staging		The method used to determine the staging of the axillary lymph node, if it was not included in the provided list.
38	3086152	Was IHC Keratin Staining Used to Detect Microscopic Metastasis?	☐ Yes ☐ No ☐ Unknown	Indication of whether immunohistochemistry was used to determine the presence of microscopic metastatic disease.
39	2200396	Were lymph nodes examined at the time of pathologic diagnosis?	☐ Yes ☐ No ☐ Unknown	Indication of whether lymph nodes were examined at the time of initial pathologic diagnosis.
40	3	Number of Lymph Nodes Examined at the Time of Pathologic Diagnosis		The number of lymph nodes examined at the time of initial pathologic diagnosis.
41	3086388	Number of Lymph Nodes Positive by H&E Light Microscopy Only at the Time of Pathologic Diagnosis		The number of lymph nodes determined to be positive by hematoxylin and eosin stain at the time of initial pathologic diagnosis.

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#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
42	3086383	Number of Lymph Nodes Positive by IHC Keratin Staining Only at the Time of Pathologic Diagnosis		The number of lymph nodes determined to be positive by immunohistochemistry at the time of initial pathologic diagnosis.
43	3124499	Site of First Non-Nodal Metastatic Tumor at Initial Diagnosis *(select all that apply)*	☐ Lung ☐ Bone ☐ Liver ☐ Brain ☐ Unknown ☐ Other (Please Specify)	The anatomic site of non-nodal metastatic disease discovered at the time the patient was initially diagnosed with the tumor that yielded the submitted sample.
44	3124503	Other Site of First Non-Nodal Metastatic Tumor		The anatomic site of non-nodal metastatic disease discovered at the time the patient was initially diagnosed with the tumor that yielded the submitted sample, if it was not included in the provided list.
45	3370189	What type of staging information is available for this diagnosis? *(select all that apply)*	☐ Pathologic ☐ Clinical	The type of staging completed for the patient at initial diagnosis and available at the TSS.
46	2722309	AJCC Cancer Staging Handbook Edition	☐ First Edition (1978-1983) ☐ Second Edition (1984-1988) ☐ Third Edition (1989-1992) ☐ Fourth Edition (1993-1997) ☐ Fifth Edition (1998-2002) ☐ Sixth Edition (2003-2009) ☐ Seventh Edition (2010- Current)	The staging edition used to stage this primary malignancy.
47	3045435	Pathologic Primary Tumor (pT)	☐ T0 ☐ Tis ☐ Tis (DCIS) ☐ Tis (LCIS) ☐ Tis (Paget's) ☐ T1mi ☐ T1 ☐ T1a ☐ T1b ☐ T1c ☐ T2 ☐ T2a ☐ T2b ☐ T3 ☐ T3a ☐ T3b ☐ T4 ☐ T4a ☐ T4b ☐ T4c ☐ T4d ☐ TX	The primary tumor spread at diagnosis, based on the AJCC classifications and the patient's diagnostic pathology review.

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#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
48	3203106	Pathologic Regional Lymph Nodes (pN)	☐ N0 ☐ N0 (i-) ☐ N0 (i+) ☐ N0 (mol-) ☐ N0 (mol+) ☐ N1mi ☐ N1 ☐ N1a ☐ N1b ☐ N1bi ☐ N1bii ☐ N1biii ☐ N1biv ☐ N1c ☐ N2 ☐ N2a ☐ N2b ☐ N3 ☐ N3a ☐ N3b ☐ N3c ☐ NX	The regional lymph node involvement at diagnosis based on the AJCC classifications and the patient's diagnostic pathology review.
49	3045439	Pathologic Distant Metastases (pM)	☐ M0 ☐ M1 ☐ MX	The presence of distant metastasis at diagnosis based on the AJCC classifications and the patient's diagnostic pathology review.
50	3203222	Pathologic Stage	☐ Stage 0 ☐ Stage I ☐ Stage IA ☐ Stage IB ☐ Stage II ☐ Stage IIA ☐ Stage IIB ☐ Stage III ☐ Stage IIIA ☐ Stage IIIB ☐ Stage IIIC ☐ Stage IV	The patient's overall stage based on the primary tumor spread, nodal involvement, and the presence of metastases based on the AJCC classifications and the patient's diagnostic pathology review.
51	3440328	Clinical Primary Tumor (cT)	☐ T0 ☐ Tis ☐ Tis (DCIS) ☐ Tis (LCIS) ☐ Tis (Paget's) ☐ T1mi ☐ T1 ☐ T1a ☐ T1b ☐ T1c ☐ T2 ☐ T2a ☐ T2b ☐ T3 ☐ T3a ☐ T3b ☐ T4 ☐ T4a ☐ T4b ☐ T4c ☐ T4d ☐ TX	The primary tumor spread at diagnosis, based on the AJCC classifications and the patient's diagnostic clinical evaluation (including scans and physical exams).
52	3440330	Clinical Regional Lymph Nodes (cN)	☐ N0 ☐ N0 (i-) ☐ N0 (i+) ☐ N0 (mol-) ☐ N0 (mol+) ☐ N1mi ☐ N1 ☐ N1a ☐ N1b ☐ N1bi ☐ N1bii ☐ N1biii ☐ N1biv ☐ N1c ☐ N2 ☐ N2a ☐ N2b ☐ N3 ☐ N3a ☐ N3b ☐ N3c ☐ NX	The regional lymph node involvement at diagnosis based on the AJCC classifications and the patient's diagnostic clinical evaluation (including scans and physical exams).
53	3440331	Clinical Distant Metastases (cM)	☐ M0 ☐ cM0 (i+) ☐ M1 ☐ MX	The presence of distant metastasis at diagnosis based on the AJCC classifications and the patient's diagnostic clinical evaluation (including scans and physical exams).
54	3440332	Clinical Stage	☐ Stage 0 ☐ Stage I ☐ Stage IA ☐ Stage IB ☐ Stage II ☐ Stage IIA ☐ Stage IIB ☐ Stage III ☐ Stage IIIA ☐ Stage IIIB ☐ Stage IIIC ☐ Stage IV	The patient's overall stage based on the primary tumor spread, nodal involvement, and the presence of metastases based on the AJCC classifications and the patient's diagnostic clinical evaluation (including scans and physical exams).

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Molecular/Genomic Information

#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
55	2957359	Estrogen Receptor (ER) Status	☐ Positive ☐ Negative ☐ Indeterminate ☐ Not Performed ☐ Unknown	The patient's estrogen receptor status at the time of diagnosis.
56	3128341	Estrogen Receptor (ER) IHC Percent (%) Positive	☐ < 1% ☐ 1-10% ☐ 11-20% ☐ 21-30% ☐ 31-40% ☐ 41-50% ☐ 51-60% ☐ 61-70% ☐ 71-80% ☐ 81-90% ☐ 91-100% ☐ Unknown	The patient's estrogen receptor percent positive based on immunohistochemistry analysis.
57	3261503	What was the cutoff percentage used to determine positivity for ER status?	(%)	The cutoff percentage used by the institution performing the IHC testing used to determine whether the patient was positive or negative for the estrogen receptor (ER).
58	5154371	If a method other than IHC was used to determine ER Status, what method was used?		If an additional or alternative method was used to determine the patient's estrogen receptor status, the specific method used.
59	5154374	If a method other than IHC was used to determine ER Status, what were the results?		If an additional or alternative method was used to determine the patient's estrogen receptor status, the patient's results for this test.
60	2957357	Progesterone Receptor (PR) Status	☐ Positive ☐ Negative ☐ Indeterminate ☐ Not Performed ☐ Unknown	The patient's progesterone receptor status at the time of diagnosis.
61	3128342	Progesterone Receptor (PR) IHC Percent (%) Positive	☐ < 1% ☐ 1-10% ☐ 11-20% ☐ 21-30% ☐ 31-40% ☐ 41-50% ☐ 51-60% ☐ 61-70% ☐ 71-80% ☐ 81-90% ☐ 91-100% ☐ Unknown	The patient's progesterone receptor percent positive based on immunohistochemistry analysis.
62	3261558	What was the cutoff percentage used to determine positivity for PR status?	(%)	The cutoff percentage used by the institution performing the IHC testing used to determine whether the patient was positive or negative for the progesterone receptor (PR).
63	5154372	If a method other than IHC was used to determine PR Status, what method was used?		If an additional or alternative method was used to determine the patient's progesterone receptor status, the specific method used.

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#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
64	5154375	If a method other than IHC was used to determine PR Status, what were the results?		If an additional or alternative method was used to determine the patient's progesterone receptor status, the patient's results for this test.
65	2957563	HER2/ERBB2 IHC Status	☐ Positive ☐ Negative ☐ Indeterminate ☐ Not Performed ☐ Unknown	The patient's HER2/ERBB2 status at the time of diagnosis.
66	3086980	IHC HER2/ERBB2% Positive	☐ < 1% ☐ 1-10% ☐ 11-20% ☐ 21-30% ☐ 31-40% ☐ 41-50% ☐ 51-60% ☐ 61-70% ☐ 71-80% ☐ 81-90% ☐ 91-100% ☐ Unknown	The patient's HER2/ERBB2 percent positive based on immunohistochemistry analysis.
67	2178402	HER2/ERBB2 IHC Intensity Score	☐ 0 ☐ +1 ☐ +2 ☐ +3 ☐ Indeterminate ☐ Not Performed ☐ Unknown	The immunohistochemistry intensity used to define HER2/ERBB2 positivity when the patient was tested.
68	2854089	HER2/ERBB2 FISH Status	☐ Positive ☐ Negative ☐ Indeterminate ☐ Not Performed ☐ Unknown	The patient's HER2/ERBB2 status as determined by fluorescence in situ hybridization (FISH) at the time of diagnosis.
69	3133738	HER2 Copy Number		The patient's HER2 copy number variation.
70	3104295	Centromere 17 Copy Number		The patient's centromere 17 copy number variation.
71	3087902	Number of Cells Counted for HER2 & Centromere 17 Copy Numbers		The number of cells counted during FISH analysis for HER2 & centromere 17 copy numbers.
72	2497552	HER2/Centromere 17 Ratio		The ratio of the copy number outcomes after FISH analysis for HER2 and centromere 17 (e.g. If both HER2 and centromere 17 copy numbers equaled 2, the ratio would be 2:2 or 1.0).
73	5154377	What was the HER2/Centromere 17 cutoff ratio used to determine a patient's positivity?		The cutoff ratio used by the institution performing the FISH testing used to determine whether the patient was positive or negative for HER2/ERBB2.
74	5154373	If a method other than IHC OR FISH was used to determine HER2/ERBB2 Status, what method was used?		If an additional or alternative method was used to determine the patient's HER2/ERBB2 status, the specific method used.
75	5154376	If a method other than IHC OR FISH was used to determine HER2/ERBB2 Status, what were the results?		If an additional or alternative method was used to determine the patient's HER2/ERBB2 status, the patient's results for this test.

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Treatment Information

#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
76	3382737	Pre-Operative Treatment for Submitted Sample (Prior to Sample Procurement)	☐ None ☐ Radiation Prior to Sample Procurement ☐ Pharmaceutical Treatment Prior to Procurement ☐ Both Pharmaceutical Treatment and Radiation Prior to Sample Procurement ☐ Unknown	Describes whether the submitting TSS knows if the patient received treatment prior to the operation that yielded the submitted sample. Pharmaceutical therapy includes chemotherapy, immunotherapy, targeted therapy, and hormone therapy. Systemic therapy and certain localized therapies (those administered to the same site as the submitted tissue) given prior to the procurement of the sample submitted are exclusionary.
77	2005312	Post-Operative Radiation Therapy (Following Sample Procurement)	☐ Yes ☐ No ☐ Unknown	Describes whether the submitting TSS knows if the patient received radiation after surgery. If surgery was not performed, indicate whether the patient received radiation after the submitted sample was procured by biopsy or other method.
78	3397567	Post-Operative Pharmaceutical Therapy (Following Sample Procurement)	☐ Yes ☐ No ☐ Unknown	Describes whether the submitting TSS knows if the patient received pharmaceutical therapy after surgery. If surgery was not performed, indicate whether the patient received pharmaceutical therapy after the submitted sample was procured by biopsy or other method. Pharmaceutical therapy includes chemotherapy, immunotherapy, targeted therapy, and hormone therapy.
79	2786727	Measure of Success of Outcome at the Completion of First Course Treatment (including surgery)	☐ Complete Response ☐ Partial Response ☐ Treatment Stopped Due to Toxicity ☐ First Course Treatment Still in Progress ☐ Unknown	The status of the patient's disease after the first course of treatment.

The repeating questions below should be completed for all types of treatment the patient received for the tumor that yielded the submitted sample. If additional sections are needed, reference the addendum where an additional page(s) of treatment information can be completed.

80	81	82	83	84*	85*
Is this first course treatment for the submitted primary tumor?	**Treatment Type**	**Agent Name**	**Treatment Outcome**	**Start Date**	**End Date**
5598548	5102381	4285089	5102383	5102384, 5102385, 5102386	5102387, 5102388, 5102389
Indicates if the treatment the patient received was first course treatment for the tumor that yielded the submitted sample.	The type of treatment administered for the tumor that yielded the submitted sample.	The name of the agent administered.	The patient's final outcome after the treatment was administered.	The first date this agent was administered. *Note: Repeating interval information can be provided using OpenClinica or the spreadsheet version of this form.*	The last date this agent was administered. *Note: Repeating interval information can be provided using OpenClinica or the spreadsheet version of this form..*

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80	81	82	83	84*	85*
Is this first course treatment for the submitted primary tumor?	**Treatment Type**	**Agent Name**	**Treatment Outcome**	**Start Date**	**End Date**
☐ Yes ☐ No	☐ Surgery Only ☐ External Radiation ☐ Internal Radiation ☐ Systemic Radiation ☐ Radiation (NOS) ☐ Chemotherapy ☐ Hormone Therapy ☐ Immunotherapy ☐ Targeted Molecular Therapy ☐ Other		☐ Complete Response ☐ Partial Response ☐ Treatment Stopped Due to Toxicity ☐ Treatment Ongoing ☐ Unknown	Month: __ __ Day: __ __ Year: __ __ __ __	Month: __ __ Day: __ __ Year: __ __ __ __

New Tumor Information

#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
86	3121376	New Tumor Event?	☐ Yes ☐ No ☐ Unknown	Describes whether the submitting TSS knows whether the patient had a new tumor event after the initial diagnosis of the tumor that yielded the submitted sample. New events include progression, recurrence and metastasis of the tumor that yielded the submitted sample, as well as new primary tumors.

The repeating questions below should be completed for all new tumor events diagnosed after the initial diagnosis of the tumor that yielded the submitted sample. If additional sections are needed, reference the addendum where an additional page(s) of new tumor event information can be completed.

87	88*	89	90	91	92
New Event Type	**Date of New Event**	**Site of New Event**	**Other Site of New Event**	**New Event Treatment Type** *(check all that apply)*	**Treatment Outcome**
3119721	3104044, 3104042, 3104046	3108271	3128033	5102391	5102392
Type of event that occurred.	The date the new tumor was diagnosed.	Anatomic site of the new tumor.	Free text anatomic site if not included in provided list.	Type of treatment received for the new tumor.	Response to treatment for new tumor.
☐ Progression ☐ Recurrence ☐ Metastasis ☐ New Primary Diagnosis	Month: __ __ Day: __ __ Year: __ __ __ __	☐ Lung ☐ Liver ☐ Brain ☐ Bone ☐ Lymph Nodes ☐ Other (Please Specify)		☐ Surgery ☐ Pharmaceutical Therapy ☐ Radiation Therapy ☐ Other Treatment Type	☐ Complete Response ☐ Partial Response ☐ Treatment Stopped Due to Toxicity ☐ Treatment Ongoing ☐ Unknown
☐ Progression ☐ Recurrence ☐ Metastasis ☐ New Primary Diagnosis	Month: __ __ Day: __ __ Year: __ __ __ __	☐ Lung ☐ Liver ☐ Brain ☐ Bone ☐ Lymph Nodes ☐ Other (Please Specify)		☐ Surgery ☐ Pharmaceutical Therapy ☐ Radiation Therapy ☐ Other Treatment Type	☐ Complete Response ☐ Partial Response ☐ Treatment Stopped Due to Toxicity ☐ Treatment Ongoing ☐ Unknown

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Survival Information

#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
93*	5116087 5116088 5116089	Most Recent Date of Last Contact	Month: __ __ Day: __ __ Year: __ __ __ __	The date of last contact with the patient, as reported by the patient, medical provider, family member or caregiver. If the patient is deceased, please use the date of death.

The repeating questions below should be completed for any date when the patient's Tumor Status changed between the date of diagnosis and the most recent date of contact or death documented in #93. If follow-up details are not available, a minimum of one entry for the most recent date of last contact or death should be completed. If additional sections are needed, reference the addendum where an additional page(s) of follow-up information can be completed.

94*	95	96
Date of Follow-up	**Tumor Status**	**Vital Status**
2897020 2897022 2897024	2759550	5
The date when the TSS learned the patient's tumor status changed.	The patient's tumor status at the date of follow-up listed.	The patient's vital status at the date of follow-up listed.
Month: __ __ Day: __ __ Year: __ __ __ __	☐ Tumor Free at Follow-up ☐ Never Tumor Free ☐ New Tumor Event (remission/relapse) ☐ Unknown	☐ Living ☐ Deceased
Month: __ __ Day: __ __ Year: __ __ __ __	☐ Tumor Free at Follow-up ☐ Never Tumor Free ☐ New Tumor Event (remission/relapse) ☐ Unknown	☐ Living ☐ Deceased

#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
97*	2897026 2897028 2897030	Date of Death	Month: __ __ Day: __ __ Year: __ __ __ __	The date the patient died.
98	2554674	Cause of Death	☐ Submitted Malignancy and/or related tumor event ☐ Other Malignancy (Please Specify) ☐ Other Non-Malignant Disease (Please Specify) ☐ Death Not Caused by Disease ☐ Unknown Cause of Death	Indicates the patient's cause of death, if known.
99	2004150	Other Cause of Death		Free text further describing the patient's cause of death.
100	2970715	Comorbidities *(check all that apply)*	*See OpenClinica or BCR Submission Spreadsheet for complete list of values.*	Other known diseases the patient had at the time of death.
101	61333	Is the patient lost to follow-up?	☐ Yes ☐ No ☐ Unknown	Indicates that the patient is lost to follow-up, as defined by the ACoS Commission on Cancer. This only includes cases where updated follow-up information has not been collected within the past 15 months and all efforts to contact the patient have been exhausted.

**If time intervals are being provided in lieu of dates (month and year at a minimum), these questions can be found in the "Time Interval" section of the addendum on page 16.*

Addendum

The following pages have been added for repeating questions when additional information is available for a single patient. In addition, a section has been added with questions regarding time intervals that can be provided in lieu of dates.

Additional Treatment Information

80	81	82	83	84*	85*
Is this first course treatment for the submitted primary tumor?	**Treatment Type**	**Agent Name**	**Treatment Outcome**	**Start Date**	**End Date**
5598548	5102381	4285089	5102383	5102384, 5102385, 5102386	5102387, 5102388, 5102389
Indicates if the treatment the patient received was first course treatment for the tumor that yielded the submitted sample.	The type of treatment administered for the tumor that yielded the submitted sample.	The name of the agent administered.	The patient's final outcome after the treatment was administered.	The first date this agent was administered. *Note: Repeating interval information can be provided using OpenClinica or the spreadsheet version of this form.*	The last date this agent was administered. *Note: Repeating interval information can be provided using OpenClinica or the spreadsheet version of this form..*
☐ Yes ☐ No	☐ Surgery Only ☐ External Radiation ☐ Internal Radiation ☐ Systemic Radiation ☐ Radiation (NOS) ☐ Chemotherapy ☐ Hormone Therapy ☐ Immunotherapy ☐ Targeted Molecular Therapy ☐ Other		☐ Complete Response ☐ Partial Response ☐ Treatment Stopped Due to Toxicity ☐ Treatment Ongoing ☐ Unknown	Month: __ __ Day: __ __ Year: __ __ __ __	Month: __ __ Day: __ __ Year: __ __ __ __
☐ Yes ☐ No	☐ Surgery Only ☐ External Radiation ☐ Internal Radiation ☐ Systemic Radiation ☐ Radiation (NOS) ☐ Chemotherapy ☐ Hormone Therapy ☐ Immunotherapy ☐ Targeted Molecular Therapy ☐ Other		☐ Complete Response ☐ Partial Response ☐ Treatment Stopped Due to Toxicity ☐ Treatment Ongoing ☐ Unknown	Month: __ __ Day: __ __ Year: __ __ __ __	Month: __ __ Day: __ __ Year: __ __ __ __

**If time intervals are being provided in lieu of dates (month and year at a minimum), these questions can be found in the "Time Interval" section of the addendum on page 16.*

Additional New Tumor Event Information

87	88*	89	90	91	92
New Event Type	**Date of New Event**	**Site of New Event**	**Other Site of New Event**	**New Event Treatment Type** *(check all that apply)*	**Treatment Outcome**
3119721	3104044 3104042 3104046	3108271	3128033	5102391	5102392
Type of event that occurred.	The date the new tumor was diagnosed.	Anatomic site of the new tumor.	Free text anatomic site if not included in provided list.	Type of treatment received for the new tumor.	Response to treatment for new tumor.
☐ Progression ☐ Recurrence ☐ Metastasis ☐ New Primary Diagnosis	Month: __ __ Day: __ __ Year: __ __ __ __	☐ Lung ☐ Liver ☐ Brain ☐ Bone ☐ Lymph Nodes ☐ Other (Please Specify)		☐ Surgery ☐ Pharmaceutical Therapy ☐ Radiation Therapy ☐ Other Treatment Type	☐ Complete Response ☐ Partial Response ☐ Treatment Stopped Due to Toxicity ☐ Treatment Ongoing ☐ Unknown
☐ Progression ☐ Recurrence ☐ Metastasis ☐ New Primary Diagnosis	Month: __ __ Day: __ __ Year: __ __ __ __	☐ Lung ☐ Liver ☐ Brain ☐ Bone ☐ Lymph Nodes ☐ Other (Please Specify)		☐ Surgery ☐ Pharmaceutical Therapy ☐ Radiation Therapy ☐ Other Treatment Type	☐ Complete Response ☐ Partial Response ☐ Treatment Stopped Due to Toxicity ☐ Treatment Ongoing ☐ Unknown
☐ Progression ☐ Recurrence ☐ Metastasis ☐ New Primary Diagnosis	Month: __ __ Day: __ __ Year: __ __ __ __	☐ Lung ☐ Liver ☐ Brain ☐ Bone ☐ Lymph Nodes ☐ Other (Please Specify)		☐ Surgery ☐ Pharmaceutical Therapy ☐ Radiation Therapy ☐ Other Treatment Type	☐ Complete Response ☐ Partial Response ☐ Treatment Stopped Due to Toxicity ☐ Treatment Ongoing ☐ Unknown
☐ Progression ☐ Recurrence ☐ Metastasis ☐ New Primary Diagnosis	Month: __ __ Day: __ __ Year: __ __ __ __	☐ Lung ☐ Liver ☐ Brain ☐ Bone ☐ Lymph Nodes ☐ Other (Please Specify)		☐ Surgery ☐ Pharmaceutical Therapy ☐ Radiation Therapy ☐ Other Treatment Type	☐ Complete Response ☐ Partial Response ☐ Treatment Stopped Due to Toxicity ☐ Treatment Ongoing ☐ Unknown
☐ Progression ☐ Recurrence ☐ Metastasis ☐ New Primary Diagnosis	Month: __ __ Day: __ __ Year: __ __ __ __	☐ Lung ☐ Liver ☐ Brain ☐ Bone ☐ Lymph Nodes ☐ Other (Please Specify)		☐ Surgery ☐ Pharmaceutical Therapy ☐ Radiation Therapy ☐ Other Treatment Type	☐ Complete Response ☐ Partial Response ☐ Treatment Stopped Due to Toxicity ☐ Treatment Ongoing ☐ Unknown

**If time intervals are being provided in lieu of dates (month and year at a minimum), these questions can be found in the "Time Interval" section of the addendum on page 16.*

Additional Survival Information

94*	95	96
Date of Follow-up	**Tumor Status**	**Vital Status**
2897020 2897022 2897024	2759550	5
The date when the TSS learned the patient's tumor status changed.	The patient's tumor status at the date of follow-up listed.	The patient's vital status at the date of follow-up listed.
Month: __ __ Day: __ __ Year: __ __ __ __	☐ Tumor Free at Follow-up ☐ Never Tumor Free ☐ New Tumor Event (remission/relapse) ☐ Unknown	☐ Living ☐ Deceased
Month: __ __ Day: __ __ Year: __ __ __ __	☐ Tumor Free at Follow-up ☐ Never Tumor Free ☐ New Tumor Event (remission/relapse) ☐ Unknown	☐ Living ☐ Deceased
Month: __ __ Day: __ __ Year: __ __ __ __	☐ Tumor Free at Follow-up ☐ Never Tumor Free ☐ New Tumor Event (remission/relapse) ☐ Unknown	☐ Living ☐ Deceased
Month: __ __ Day: __ __ Year: __ __ __ __	☐ Tumor Free at Follow-up ☐ Never Tumor Free ☐ New Tumor Event (remission/relapse) ☐ Unknown	☐ Living ☐ Deceased
Month: __ __ Day: __ __ Year: __ __ __ __	☐ Tumor Free at Follow-up ☐ Never Tumor Free ☐ New Tumor Event (remission/relapse) ☐ Unknown	☐ Living ☐ Deceased
Month: __ __ Day: __ __ Year: __ __ __ __	☐ Tumor Free at Follow-up ☐ Never Tumor Free ☐ New Tumor Event (remission/relapse) ☐ Unknown	☐ Living ☐ Deceased
Month: __ __ Day: __ __ Year: __ __ __ __	☐ Tumor Free at Follow-up ☐ Never Tumor Free ☐ New Tumor Event (remission/relapse) ☐ Unknown	☐ Living ☐ Deceased

**If time intervals are being provided in lieu of dates (month and year at a minimum), these questions can be found in the "Time Interval" section of the addendum on page 16.*

Time Intervals

The following questions are not relevant for any TSS that has provided complete or partial (minimum of month and year) dates for any questions on this form asking for a date. If a TSS is not able to provide a full date or partial date, due to an Internal Review Board requirement, the following time intervals should be completed as defined. Please note that these intervals should begin and end with the exact time points described.

#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
4-ALT	3008233	Number of days from Date of Initial Pathologic Diagnosis to the **Date of Birth**		The number of days between the initial pathologic diagnosis and the date the patient was born.
20-ALT	5102380	Number of days from Date of Initial Pathologic Diagnosis to the **Date of Clinical Diagnosis**		The number of days between the initial pathologic diagnosis and the date the patient was clinically diagnosed with the tumor that yielded the submitted sample.
84-ALT	5102411	Number of days from Date of Initial Pathologic Diagnosis to the **Date the Agent used to Treat the Patient was First Administered**		The number of days between the initial pathologic diagnosis and the first date this agent was administered.
85-ALT	5102431	Number of days from Date of Initial Pathologic Diagnosis to the **Date the Agent used to Treat the Patient was Last Administered**		The number of days between the initial pathologic diagnosis and the last date this agent was administered.
88-ALT	3392464	Number of days from Date of Initial Pathologic Diagnosis to the **Date of New Tumor Event**		The number of days between the initial pathologic diagnosis and the date the new tumor was diagnosed.
93-ALT	5116090	Number of days from Date of Initial Pathologic Diagnosis to the **Date of Most Recent Last Contact**		The number of days between the initial pathologic diagnosis and the most recent date of last contact with the patient, as reported by the patient, medical provider, family member or caregiver. If the patient is deceased, please use the date of death.
94-ALT	3008273	Number of days from Date of Initial Pathologic Diagnosis to the **Date of Follow-up**		The number of days between the initial pathologic diagnosis and the date when the TSS learned the patient's tumor status changed.
97-ALT	3165475	Number of days from Date of Initial Pathologic Diagnosis to the **Date of Death**		The number of days between the initial pathologic diagnosis and the date of death

**If time intervals are being provided in lieu of dates (month and year at a minimum), these questions can be found in the "Time Interval" section of the addendum on page 16.*