

# Clinical Data Form

## Colon Adenocarcinoma (COAD)

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	<input type="checkbox"/> Recruiting <input type="checkbox"/> Active; not recruiting <input type="checkbox"/> Completed <input type="checkbox"/> Suspended <input type="checkbox"/> Terminated	Indicates the status of the protocol used to procure the submitted sample, at the time the sample was submitted for this project. <b>Recruiting:</b> Participants were still being recruited <b>Active:</b> Study ongoing, but participants were not being recruited <b>Completed:</b> Study concluded and patients were no longer being examined or treated <b>Suspended:</b> Recruiting and enrollment was halted prematurely but may resume <b>Terminated:</b> 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	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> 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)	<input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Asian <input type="checkbox"/> White <input type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Not Reported <input type="checkbox"/> Unknown	The patient's self-reported race. <b>American Indian or Alaska Native:</b> 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. <b>Asian:</b> 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. <b>White:</b> A person having origins in any of the original peoples of Europe, the Middle East, or North Africa. <b>Black or African American:</b> 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." <b>Native Hawaiian or other Pacific Islander:</b> A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island.

#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
6	2192217	Ethnicity	<input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Reported <input type="checkbox"/> Unknown	The patient's self-described ethnicity. <b>Not Hispanic or Latino:</b> A person not meeting the definition of Hispanic or Latino. <b>Hispanic or Latino:</b> 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?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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? (check all that apply)	<input type="checkbox"/> Radiation <input type="checkbox"/> Chemotherapy <input type="checkbox"/> Other <input type="checkbox"/> Unknown	Indicates whether the patient received radiation, chemotherapy or another type of treatment for a prior or synchronous malignancy.														
11	2185953	Did the patient have a history of synchronous colon or rectal tumor(s) at the time of tissue collection?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicates whether the patient had a synchronous colon or rectal malignancy at the time the tumor that yielded the submitted sample was removed.														
12	3107197	Did the patient have a history of colon polyps at the time of tissue collection?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicates whether the patient was known to have a history of colon polyps at the time the tumor that yielded the submitted sample was removed.														
13	64184	Were colon polyps present at the time of tissue collection?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicates whether there was evidence of colon polyps at the time the tumor that yielded the submitted sample was removed.														
14	2691192	Does the patient have a family history (first degree relatives only) of cancer?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicates whether any of the patient's first degree relatives (including parents, siblings and children) have a history of cancer.														
15	2783641 3457764	If the patient has a family history of cancer, indicate the family member and type of cancer.	<table border="1"> <thead> <tr> <th>Family member</th> <th>Site of cancer</th> </tr> </thead> <tbody> <tr> <td><input type="checkbox"/> Mother</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Father</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Sister</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Brother</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Daughter</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Son</td> <td></td> </tr> </tbody> </table>	Family member	Site of cancer	<input type="checkbox"/> Mother		<input type="checkbox"/> Father		<input type="checkbox"/> Sister		<input type="checkbox"/> Brother		<input type="checkbox"/> Daughter		<input type="checkbox"/> 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.
Family member	Site of cancer																	
<input type="checkbox"/> Mother																		
<input type="checkbox"/> Father																		
<input type="checkbox"/> Sister																		
<input type="checkbox"/> Brother																		
<input type="checkbox"/> Daughter																		
<input type="checkbox"/> Son																		
16	3107205	Number of First Degree Relatives with a history of Colon or Rectal Cancer	<input type="checkbox"/> 0 <input type="checkbox"/> 3 <input type="checkbox"/> 1 <input type="checkbox"/> >3 <input type="checkbox"/> 2 <input type="checkbox"/> Unknown	Indicates the number of first degree relatives who were known to have a history of colon or rectal cancer.														

#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
17	2181650	Tobacco Smoking Status at the Time of Diagnosis	<input type="checkbox"/> Lifelong non-smoker <input type="checkbox"/> Smoker at diagnosis <input type="checkbox"/> Reformed smoker at diagnosis <b>for more than 15 years</b> <input type="checkbox"/> Reformed smoker at diagnosis <b>for 15 years or less</b> <input type="checkbox"/> Reformed smoker at diagnosis <b>duration unknown</b> <input type="checkbox"/> Smoking history not documented	The patient’s self-reported history of tobacco smoking. <b>Lifelong non-smoker:</b> Someone who has smoked <100 cigarettes during their lifetime. <b>Smoker at diagnosis:</b> Someone who was a daily or occasional smoker at diagnosis. <b>Reformed smoker:</b> Someone who was previously a daily or occasional smoker, but at the time of diagnosis was no longer smoking.
18	2228604	Tobacco Smoking Year of Onset		The year the patient began smoking.
19	2228610	Tobacco Smoking Year of Quitting		The year the patient stopped smoking.
20	2955385	Number of Pack Years Smoked		The patient’s lifetime exposure, calculated with the following equation: $(\# \text{ Cigarettes Smoked per Day})(\text{Years Smoked}) / 20$ <i>The number of cigarettes smoked per day multiplied by the years smoked and divided by 20.</i>
21	88	Performance Status Scale: Eastern Cooperative Oncology Group (ECOG) at Time of Diagnosis	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 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
22	2003853	Performance Status Score: Karnofsky Score at Time of Diagnosis	<input type="checkbox"/> 100 <input type="checkbox"/> 90 <input type="checkbox"/> 80 <input type="checkbox"/> 70 <input type="checkbox"/> 60 <input type="checkbox"/> 50 <input type="checkbox"/> 40 <input type="checkbox"/> 30 <input type="checkbox"/> 20 <input type="checkbox"/> 10 <input type="checkbox"/> 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

**Diagnostic/Pathologic Information**

#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
23*	5102356 5102357 5102358	Date of Clinical Diagnosis	Month: ____ Day: ____ Year: ____ ____ ____	The date the patient was clinically diagnosed with the primary malignancy, based on a clinical exam, scan, or pathologic review of a biopsy or surgical resection.

\*If time intervals are being provide din 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.

#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
24	5102378	Method of Clinical Diagnosis	<input type="checkbox"/> Physical Exam <input type="checkbox"/> Imaging (X-ray; Scan; Ultrasound; etc.) <input type="checkbox"/> Biochemical Evidence of Disease <input type="checkbox"/> Cytology <input type="checkbox"/> Other	The method used to clinically diagnose the primary malignancy.
25*	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.
26	2757941	Method of Initial Pathologic Diagnosis	<input type="checkbox"/> Left Hemicolectomy <input type="checkbox"/> Right Hemicolectomy <input type="checkbox"/> Transverse Colectomy <input type="checkbox"/> Sigmoid Colectomy <input type="checkbox"/> Total Colectomy <input type="checkbox"/> Pan-Procto Colectomy <input type="checkbox"/> Low Anterior Colon Resection <input type="checkbox"/> Other (Please Specify)	The procedure performed to procure the sample used for the initial pathologic diagnosis.
27	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.
28	3427536	Primary Site of Disease	<input type="checkbox"/> Colon	The anatomic site of the primary tumor that yielded the submitted sample.
29	3108203	Region of the Primary Malignancy in the Colon <i>(select all that apply)</i>	<input type="checkbox"/> Cecum <input type="checkbox"/> Ascending Colon <input type="checkbox"/> Hepatic Flexure <input type="checkbox"/> Transverse Colon <input type="checkbox"/> Splenic Flexure <input type="checkbox"/> Descending Colon <input type="checkbox"/> Sigmoid Colon	The region(s) of the colon where the primary tumor that yielded the submitted sample was located.
30	3081934	Histological Subtype	<input type="checkbox"/> Adenocarcinoma <input type="checkbox"/> Mucinous Adenocarcinoma	The histologic diagnosis of the entire tumor that yielded the submitted sample, determined at the date of initial pathologic diagnosis.
31	2608702	Residual Tumor	<input type="checkbox"/> R0 <input type="checkbox"/> RX <input type="checkbox"/> R1 <input type="checkbox"/> Not Evaluated <input type="checkbox"/> R2	The absence or presence of tumor after the patient’s surgery for primary tumor. <b>R0</b> (No residual tumor) <b>R2</b> (Macroscopic residual tumor) <b>R1</b> (Microscopic residual tumor) <b>RX</b> (Residual tumor cannot be assessed)
32	5457224	First Surgical Procedure	<input type="checkbox"/> Left Hemicolectomy <input type="checkbox"/> Right Hemicolectomy <input type="checkbox"/> Transverse Colectomy <input type="checkbox"/> Sigmoid Colectomy <input type="checkbox"/> Total Colectomy <input type="checkbox"/> Pan-Procto Colectomy <input type="checkbox"/> Low Anterior Colon Resection <input type="checkbox"/> Unknown <input type="checkbox"/> Other (Please Specify)	The first surgical procedure performed to remove the tumor that yielded the submitted sample.

\*If time intervals are being provide din 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.

#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
33	3020338	Other First Surgical Procedure		The first surgical procedure performed not included in the provided list.
34	3114007	Margin Status after First Surgical Procedure	<input type="checkbox"/> Positive (+) <input type="checkbox"/> Negative (-) <input type="checkbox"/> Close <input type="checkbox"/> Unknown	The status of residual disease after the first surgical procedure was completed.
35	5457225	If the margins were positive after the first surgical procedure, what was the surgical method performed to achieve negative margins?	<input type="checkbox"/> Surgery was Not Performed <input type="checkbox"/> Left Hemicolectomy <input type="checkbox"/> Right Hemicolectomy <input type="checkbox"/> Transverse Colectomy <input type="checkbox"/> Sigmoid Colectomy <input type="checkbox"/> Total Colectomy <input type="checkbox"/> Pan-Procto Colectomy <input type="checkbox"/> Low Anterior Colon Resection <input type="checkbox"/> Unknown <input type="checkbox"/> Other (Please Specify)	The second surgical resection performed when positive margins remained after the first surgery.
36	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.
37	5457227	Margin Status after Second Surgical Procedure	<input type="checkbox"/> Positive (+) <input type="checkbox"/> Negative (-) <input type="checkbox"/> Close <input type="checkbox"/> Unknown	The status of residual disease after the second surgical procedure was completed.
38	3370189	What type of staging information is available for this diagnosis? (select all that apply)	<input type="checkbox"/> Pathologic <input type="checkbox"/> Clinical	The type of staging completed for the patient at initial diagnosis and available at the TSS.
39	2722309	AJCC Cancer Staging Handbook Edition	<input type="checkbox"/> First Edition (1978-1983) <input type="checkbox"/> Second Edition (1984-1988) <input type="checkbox"/> Third Edition (1989-1992) <input type="checkbox"/> Fourth Edition (1993-1997) <input type="checkbox"/> Fifth Edition (1998-2002) <input type="checkbox"/> Sixth Edition (2003-2009) <input type="checkbox"/> Seventh Edition (2010- Current)	The staging edition used to stage this primary malignancy.
40	3045435	Pathologic Primary Tumor (pT)	<input type="checkbox"/> T0 <input type="checkbox"/> T2 <input type="checkbox"/> T3 <input type="checkbox"/> T4b <input type="checkbox"/> Tis <input type="checkbox"/> T2a <input type="checkbox"/> T4 <input type="checkbox"/> T5 <input type="checkbox"/> T1 <input type="checkbox"/> T2b <input type="checkbox"/> T4a <input type="checkbox"/> TX	The primary tumor spread at diagnosis, based on the AJCC classifications and the patient's diagnostic pathology review.
41	3203106	Pathologic Regional Lymph Nodes (pN)	<input type="checkbox"/> N0 <input type="checkbox"/> N1b <input type="checkbox"/> N2a <input type="checkbox"/> N3 <input type="checkbox"/> N1 <input type="checkbox"/> N1c <input type="checkbox"/> N2b <input type="checkbox"/> NX <input type="checkbox"/> N1a <input type="checkbox"/> N2	The regional lymph node involvement at diagnosis based on the AJCC classifications and the patient's diagnostic pathology review.

#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
42	3045439	Pathologic Distant Metastases (pM)	<input type="checkbox"/> M0 <input type="checkbox"/> M1a <input type="checkbox"/> MX <input type="checkbox"/> M1 <input type="checkbox"/> M1b	The presence of distant metastasis at diagnosis based on the AJCC classifications and the patient's diagnostic pathology review.
43	3203222	Pathologic Stage	<input type="checkbox"/> Stage 0 <input type="checkbox"/> Stage III <input type="checkbox"/> Stage I <input type="checkbox"/> Stage IIIA <input type="checkbox"/> Stage IA <input type="checkbox"/> Stage IIIB <input type="checkbox"/> Stage IB <input type="checkbox"/> Stage IIIC <input type="checkbox"/> Stage II <input type="checkbox"/> Stage IV <input type="checkbox"/> Stage IIA <input type="checkbox"/> Stage IVA <input type="checkbox"/> Stage IIB <input type="checkbox"/> Stage IVB <input type="checkbox"/> Stage IIC	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.
44	3440328	Clinical Primary Tumor (cT)	<input type="checkbox"/> T0 <input type="checkbox"/> T2 <input type="checkbox"/> T3 <input type="checkbox"/> T4b <input type="checkbox"/> Tis <input type="checkbox"/> T2a <input type="checkbox"/> T4 <input type="checkbox"/> T5 <input type="checkbox"/> T1 <input type="checkbox"/> T2b <input type="checkbox"/> T4a <input type="checkbox"/> TX	The primary tumor spread at diagnosis, based on the AJCC classifications and the patient's diagnostic clinical evaluation (including scans and physical exams).
45	3440330	Clinical Regional Lymph Nodes (cN)	<input type="checkbox"/> N0 <input type="checkbox"/> N1c <input type="checkbox"/> N2b <input type="checkbox"/> N1 <input type="checkbox"/> N2 <input type="checkbox"/> N3 <input type="checkbox"/> N1a <input type="checkbox"/> N2a <input type="checkbox"/> NX <input type="checkbox"/> N1b	The regional lymph node involvement at diagnosis based on the AJCC classifications and the patient's diagnostic clinical evaluation (including scans and physical exams).
46	3440331	Clinical Distant Metastases (cM)	<input type="checkbox"/> M0 <input type="checkbox"/> M1a <input type="checkbox"/> MX <input type="checkbox"/> M1 <input type="checkbox"/> M1b	The presence of distant metastasis at diagnosis based on the AJCC classifications and the patient's diagnostic clinical evaluation (including scans and physical exams).
47	3440332	Clinical Stage	<input type="checkbox"/> Stage 0 <input type="checkbox"/> Stage III <input type="checkbox"/> Stage I <input type="checkbox"/> Stage IIIA <input type="checkbox"/> Stage IA <input type="checkbox"/> Stage IIIB <input type="checkbox"/> Stage IB <input type="checkbox"/> Stage IIIC <input type="checkbox"/> Stage II <input type="checkbox"/> Stage IV <input type="checkbox"/> Stage IIA <input type="checkbox"/> Stage IVA <input type="checkbox"/> Stage IIB <input type="checkbox"/> Stage IVB <input type="checkbox"/> Stage IIC	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).
48	2200396	Were lymph nodes examined at the time of pathologic diagnosis?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicates whether lymph nodes were examined at the time of initial pathologic diagnosis.
49	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.
50	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.
51	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.

#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
52	3124499	Site of First Non-Nodal Metastatic Tumor at Initial Diagnosis (select all that apply)	<input type="checkbox"/> Bone <input type="checkbox"/> Brain <input type="checkbox"/> Liver <input type="checkbox"/> Lung <input type="checkbox"/> Other (Please Specify) <input type="checkbox"/> Unknown	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.
53	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.

### Additional Prognostic Information

#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions										
54	2752	Preoperative and Pretreatment CEA Level	(Ng/mL)	The patient's carcinoembryonic antigen level prior to surgery and treatment.										
55	3107051	Non-nodal Tumor Deposits (TD) in Resected Specimen	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicates evidence of non-nodal tumor deposits in the tumor that yielded the submitted sample.										
56	64202	Circumferential Resection Margin (CRM) (Radial Surgical Clearance)	(mm)	The measured length between a malignant lesion of the colon and the nearest radial (or circumferential) border of tissue removed.										
57	64358	Vascular Invasion Present	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicates whether there was evidence of vascular invasion in the tumor that yielded the submitted sample.										
58	64171	Lymphatic Invasion Present	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicates whether there was evidence of lymphatic invasion in the tumor that yielded the submitted sample.										
59	64181	Perineural Invasion Present	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicates whether there was evidence of perineural invasion in the tumor that yielded the submitted sample.										
60	3123142	Microsatellite Instability (Abnormal @ >33% loci tested)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicates whether there was evidence of microsatellite instability when testing the tumor that yielded the submitted sample.										
61	3107127	Number of Loci Tested		The number of loci tested to detect recessive mutations.										
62	3107129	Number of Abnormal Loci		The number of loci found to be abnormal tested to detect recessive mutations.										
63	3123153	Was Loss of Expression of Mismatch Repair Proteins tested (by IHC)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicates whether a test was performed to identify any loss of expression in mismatch repair proteins by immunohistochemistry staining (IHC).										
64	3105496	Loss of Expression of Mismatch Repair Proteins by IHC	<table border="1"> <thead> <tr> <th>Expressed</th> <th>Not Expressed</th> </tr> </thead> <tbody> <tr> <td><input type="checkbox"/> MLH1</td> <td><input type="checkbox"/> MLH1</td> </tr> <tr> <td><input type="checkbox"/> MSH2</td> <td><input type="checkbox"/> MSH2</td> </tr> <tr> <td><input type="checkbox"/> PMS2</td> <td><input type="checkbox"/> PMS2</td> </tr> <tr> <td><input type="checkbox"/> MSH6</td> <td><input type="checkbox"/> MSH6</td> </tr> </tbody> </table>	Expressed	Not Expressed	<input type="checkbox"/> MLH1	<input type="checkbox"/> MLH1	<input type="checkbox"/> MSH2	<input type="checkbox"/> MSH2	<input type="checkbox"/> PMS2	<input type="checkbox"/> PMS2	<input type="checkbox"/> MSH6	<input type="checkbox"/> MSH6	Loss of expression results by immunohistochemistry.
Expressed	Not Expressed													
<input type="checkbox"/> MLH1	<input type="checkbox"/> MLH1													
<input type="checkbox"/> MSH2	<input type="checkbox"/> MSH2													
<input type="checkbox"/> PMS2	<input type="checkbox"/> PMS2													
<input type="checkbox"/> MSH6	<input type="checkbox"/> MSH6													

#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions																						
65	3123147	KRAS Gene Analysis Performed	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicates whether KRAS analysis was performed.																						
66	2932340	Was a KRAS mutation found?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	If KRAS analysis was performed, indicates whether KRAS mutations were found.																						
67	3147614	KRAS Mutation	<table border="1"> <thead> <tr> <th>DNA (c.) Changes</th> <th>Protein (p.) Changes</th> </tr> </thead> <tbody> <tr> <td><input type="checkbox"/> c.34G&gt;A</td> <td><input type="checkbox"/> p.Gly12Ser</td> </tr> <tr> <td><input type="checkbox"/> c.34G&gt;C</td> <td><input type="checkbox"/> p.Gly12Arg</td> </tr> <tr> <td><input type="checkbox"/> c.34G&gt;T</td> <td><input type="checkbox"/> p.Gly12Cys</td> </tr> <tr> <td><input type="checkbox"/> c.35G&gt;A</td> <td><input type="checkbox"/> p.Gly12Asp</td> </tr> <tr> <td><input type="checkbox"/> c.35G&gt;C</td> <td><input type="checkbox"/> p.Gly12Ala</td> </tr> <tr> <td><input type="checkbox"/> c.35G&gt;T</td> <td><input type="checkbox"/> p.Gly12Val</td> </tr> <tr> <td><input type="checkbox"/> c.37G&gt;T</td> <td><input type="checkbox"/> p.Gly13Cys</td> </tr> <tr> <td><input type="checkbox"/> c.38G&gt;A</td> <td><input type="checkbox"/> p.Gly13Asp</td> </tr> <tr> <td><input type="checkbox"/> c.183A&gt;C</td> <td><input type="checkbox"/> p.Gln61His</td> </tr> <tr> <td><input type="checkbox"/> c.436G&gt;A</td> <td><input type="checkbox"/> p.Ala146Thr</td> </tr> </tbody> </table> <input type="checkbox"/> Other Mutations (Please Specify) <input type="checkbox"/> Unknown	DNA (c.) Changes	Protein (p.) Changes	<input type="checkbox"/> c.34G>A	<input type="checkbox"/> p.Gly12Ser	<input type="checkbox"/> c.34G>C	<input type="checkbox"/> p.Gly12Arg	<input type="checkbox"/> c.34G>T	<input type="checkbox"/> p.Gly12Cys	<input type="checkbox"/> c.35G>A	<input type="checkbox"/> p.Gly12Asp	<input type="checkbox"/> c.35G>C	<input type="checkbox"/> p.Gly12Ala	<input type="checkbox"/> c.35G>T	<input type="checkbox"/> p.Gly12Val	<input type="checkbox"/> c.37G>T	<input type="checkbox"/> p.Gly13Cys	<input type="checkbox"/> c.38G>A	<input type="checkbox"/> p.Gly13Asp	<input type="checkbox"/> c.183A>C	<input type="checkbox"/> p.Gln61His	<input type="checkbox"/> c.436G>A	<input type="checkbox"/> p.Ala146Thr	<p>If KRAS mutations were found, indicate the specific mutation found.</p> <p>If the annotation available for KRAS mutations uses the single letter code for protein changes (those beginning with “p.”), use the following amino acid abbreviation table as a resource.</p> <p>Ala = Alanine (A)            Arg = Arginine (R)            Asp = Aspartic Acid (D)            Cys = Cysteine (C)            Gln = Glutamine (Q)            Gly = Glycine (G)            His = Histidine (H)            Leu = Leucine (L)            Phe = Phenylalanine (F)            Ser = Serine (S)            Thr = Threonine (T)            Val = Valine (V)</p>
DNA (c.) Changes	Protein (p.) Changes																									
<input type="checkbox"/> c.34G>A	<input type="checkbox"/> p.Gly12Ser																									
<input type="checkbox"/> c.34G>C	<input type="checkbox"/> p.Gly12Arg																									
<input type="checkbox"/> c.34G>T	<input type="checkbox"/> p.Gly12Cys																									
<input type="checkbox"/> c.35G>A	<input type="checkbox"/> p.Gly12Asp																									
<input type="checkbox"/> c.35G>C	<input type="checkbox"/> p.Gly12Ala																									
<input type="checkbox"/> c.35G>T	<input type="checkbox"/> p.Gly12Val																									
<input type="checkbox"/> c.37G>T	<input type="checkbox"/> p.Gly13Cys																									
<input type="checkbox"/> c.38G>A	<input type="checkbox"/> p.Gly13Asp																									
<input type="checkbox"/> c.183A>C	<input type="checkbox"/> p.Gln61His																									
<input type="checkbox"/> c.436G>A	<input type="checkbox"/> p.Ala146Thr																									
68	5525148	Other KRAS Mutation(s)		If the KRAS mutations found for this patient were not included in the provided list, specify the KRAS mutations found. When possible, follow the guidelines set by the Human Genome Variation Society ( <a href="http://varnomen.hgvs.org/">http://varnomen.hgvs.org/</a> ).																						
68	3123151	BRAF Gene Analysis Performed	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicates whether BRAF analysis was performed.																						
69	3107189	BRAF Gene Analysis Results	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	If BRAF analysis was performed, indicates the results of the gene analysis.																						

### Treatment Information

#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
70	3382737	Pre-Operative Treatment for Submitted Sample (Prior to Sample Procurement)	<input type="checkbox"/> None <input type="checkbox"/> Radiation Prior to Sample Procurement <input type="checkbox"/> Pharmaceutical Treatment Prior to Procurement <input type="checkbox"/> Both Pharmaceutical Treatment and Radiation Prior to Sample Procurement <input type="checkbox"/> Unknown	<p>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.</p> <p><b>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.</b></p>



#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
71	2005312	Post-Operative Radiation Therapy (Following Sample Procurement)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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.
72	3397567	Post-Operative Pharmaceutical Therapy (Following Sample Procurement)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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.
73	2786727	Measure of Success of Outcome at the Completion of First Course Treatment (including surgery)	<input type="checkbox"/> Complete Response <input type="checkbox"/> Partial Response <input type="checkbox"/> Treatment Stopped Due to Toxicity <input type="checkbox"/> First Course Treatment Still in Progress <input type="checkbox"/> Unknown	The status of the patient's disease after the first course of treatment.

The repeating questions below should be completed for all first course treatment(s) for the primary tumor submitted for this study. If additional sections are needed, reference the addendum where an additional page(s) of treatment information can be completed.

74	75	76	77	78*	79*
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. <i>Note: Repeating interval information can be provided using OpenClinica or the spreadsheet version of this form.</i>	The last date this agent was administered. <i>Note: Repeating interval information can be provided using OpenClinica or the spreadsheet version of this form..</i>
<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Surgery Only <input type="checkbox"/> External Radiation <input type="checkbox"/> Internal Radiation <input type="checkbox"/> Systemic Radiation <input type="checkbox"/> Radiation (NOS) <input type="checkbox"/> Chemotherapy <input type="checkbox"/> Hormone Therapy <input type="checkbox"/> Immunotherapy <input type="checkbox"/> Targeted Molecular Therapy <input type="checkbox"/> Other		<input type="checkbox"/> Complete Response <input type="checkbox"/> Partial Response <input type="checkbox"/> Treatment Stopped Due to Toxicity <input type="checkbox"/> Treatment Ongoing <input type="checkbox"/> Unknown	Month: ____ Day: ____ Year: ____	Month: ____ Day: ____ Year: ____

\*If time intervals are being provide din 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.

74	75	76	77	78*	79*
<b>Is this first course treatment for the submitted primary tumor?</b>	<b>Treatment Type</b>	<b>Agent Name</b>	<b>Treatment Outcome</b>	<b>Start Date</b>	<b>End Date</b>
<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Surgery Only <input type="checkbox"/> External Radiation <input type="checkbox"/> Internal Radiation <input type="checkbox"/> Systemic Radiation <input type="checkbox"/> Radiation (NOS) <input type="checkbox"/> Chemotherapy <input type="checkbox"/> Hormone Therapy <input type="checkbox"/> Immunotherapy <input type="checkbox"/> Targeted Molecular Therapy <input type="checkbox"/> Other		<input type="checkbox"/> Complete Response <input type="checkbox"/> Partial Response <input type="checkbox"/> Treatment Stopped Due to Toxicity <input type="checkbox"/> Treatment Ongoing <input type="checkbox"/> Unknown	Month: ___ Day: ___ Year: _____	Month: ___ Day: ___ Year: _____

**New Tumor Information**

#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
80	3121376	New Tumor Event	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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. <b>New events</b> 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.

81	82*	83	84	85	86
<b>New Event Type</b>	<b>Date of New Event</b>	<b>Site of New Event</b>	<b>Other Site of New Event</b>	<b>New Event Treatment Type (check all that apply)</b>	<b>Treatment Outcome</b>
3119721	3104044, 3104042, 3104046	3108271	3128033	5102391	5102392
Type of event that occurred.	The date the new tumor was diagnosed. <i>Note: Repeating interval information can be provided using OpenClinica or the spreadsheet version of this form..</i>	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.
<input type="checkbox"/> Progression <input type="checkbox"/> Recurrence <input type="checkbox"/> Metastasis <input type="checkbox"/> New Primary Diagnosis	Month: ___ Day: ___ Year: _____	<input type="checkbox"/> Lung <input type="checkbox"/> Liver <input type="checkbox"/> Brain <input type="checkbox"/> Bone <input type="checkbox"/> Lymph Nodes <input type="checkbox"/> Other (Please Specify)		<input type="checkbox"/> Surgery <input type="checkbox"/> Pharmaceutical Therapy <input type="checkbox"/> Radiation Therapy <input type="checkbox"/> Other Treatment Type	<input type="checkbox"/> Complete Response <input type="checkbox"/> Partial Response <input type="checkbox"/> Treatment Stopped Due to Toxicity <input type="checkbox"/> Treatment Ongoing <input type="checkbox"/> Unknown

\*If time intervals are being provide din 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.

81	82*	83	84	85	86
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
<input type="checkbox"/> Progression <input type="checkbox"/> Recurrence <input type="checkbox"/> Metastasis <input type="checkbox"/> New Primary Diagnosis	Month: ___ Day: ___ Year: _____	<input type="checkbox"/> Lung <input type="checkbox"/> Liver <input type="checkbox"/> Brain <input type="checkbox"/> Bone <input type="checkbox"/> Lymph Nodes <input type="checkbox"/> Other (Please Specify)		<input type="checkbox"/> Surgery <input type="checkbox"/> Pharmaceutical Therapy <input type="checkbox"/> Radiation Therapy <input type="checkbox"/> Other Treatment Type	<input type="checkbox"/> Complete Response <input type="checkbox"/> Partial Response <input type="checkbox"/> Treatment Stopped Due to Toxicity <input type="checkbox"/> Treatment Ongoing <input type="checkbox"/> Unknown

**Survival Information**

#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
87	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 #86. 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.

88	89	90
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: _____	<input type="checkbox"/> Tumor Free at Follow-up <input type="checkbox"/> Never Tumor Free <input type="checkbox"/> New Tumor Event (remission/relapse) <input type="checkbox"/> Unknown	<input type="checkbox"/> Living <input type="checkbox"/> Deceased
Month: ___ Day: ___ Year: _____	<input type="checkbox"/> Tumor Free at Follow-up <input type="checkbox"/> Never Tumor Free <input type="checkbox"/> New Tumor Event (remission/relapse) <input type="checkbox"/> Unknown	<input type="checkbox"/> Living <input type="checkbox"/> Deceased

#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
91*	2897026 2897028 2897030	Date of Death	Month: ___ Day: ___ Year: _____	The date the patient died.

\*If time intervals are being provide din 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.

#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
92	2554674	Cause of Death	<input type="checkbox"/> Submitted Malignancy and/or related tumor event <input type="checkbox"/> Other Malignancy (Please Specify) <input type="checkbox"/> Other Non-Malignant Disease (Please Specify) <input type="checkbox"/> Death Not Caused by Disease <input type="checkbox"/> Unknown Cause of Death	Indicates the patient's cause of death, if known.
93	2004150	Other Cause of Death		Free text further describing the patient's cause of death.
94	2970715	Comorbidities (check all that apply)	<i>See OpenClinica or BCR Submission Spreadsheet for complete list of values.</i>	Other known diseases the patient had at the time of death.
95	61333	Is the patient lost to follow-up?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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.

## 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

74	75	76	77	78*	79*
Is this first course treatment for the submitted primary tumor?	Treatment Type	Agent Name	Treatment Outcome	Start Date	End Date
TBD	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.	The last date this agent was administered.
<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Surgery Only <input type="checkbox"/> External Radiation <input type="checkbox"/> Internal Radiation <input type="checkbox"/> Systemic Radiation <input type="checkbox"/> Radiation (NOS) <input type="checkbox"/> Chemotherapy <input type="checkbox"/> Hormone Therapy <input type="checkbox"/> Immunotherapy <input type="checkbox"/> Targeted Molecular Therapy <input type="checkbox"/> Other		<input type="checkbox"/> Complete Response <input type="checkbox"/> Partial Response <input type="checkbox"/> Treatment Stopped Due to Toxicity <input type="checkbox"/> Treatment Ongoing <input type="checkbox"/> Unknown	Month: ___ Day: ___ Year: _____	Month: ___ Day: ___ Year: _____
<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Surgery Only <input type="checkbox"/> External Radiation <input type="checkbox"/> Internal Radiation <input type="checkbox"/> Systemic Radiation <input type="checkbox"/> Radiation (NOS) <input type="checkbox"/> Chemotherapy <input type="checkbox"/> Hormone Therapy <input type="checkbox"/> Immunotherapy <input type="checkbox"/> Targeted Molecular Therapy <input type="checkbox"/> Other		<input type="checkbox"/> Complete Response <input type="checkbox"/> Partial Response <input type="checkbox"/> Treatment Stopped Due to Toxicity <input type="checkbox"/> Treatment Ongoing <input type="checkbox"/> Unknown	Month: ___ Day: ___ Year: _____	Month: ___ Day: ___ Year: _____
<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Surgery Only <input type="checkbox"/> External Radiation <input type="checkbox"/> Internal Radiation <input type="checkbox"/> Systemic Radiation <input type="checkbox"/> Radiation (NOS) <input type="checkbox"/> Chemotherapy <input type="checkbox"/> Hormone Therapy <input type="checkbox"/> Immunotherapy <input type="checkbox"/> Targeted Molecular Therapy		<input type="checkbox"/> Complete Response <input type="checkbox"/> Partial Response <input type="checkbox"/> Treatment Stopped Due to Toxicity <input type="checkbox"/> Treatment Ongoing <input type="checkbox"/> Unknown	Month: ___ Day: ___ Year: _____	Month: ___ Day: ___ Year: _____

\*If time intervals are being provide din 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.

74	75	76	77	78*	79*
Is this first course treatment for the submitted primary tumor?	Treatment Type	Agent Name	Treatment Outcome	Start Date	End Date
	<input type="checkbox"/> Other				

**Additional New Tumor Event Information**

80	81	82	83	84	85
New Event Type	Date of New Event	Site of New Event	Other Site of New Event	New Event Treatment Type <i>(check all that apply)</i>	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.
<input type="checkbox"/> Progression <input type="checkbox"/> Recurrence <input type="checkbox"/> Metastasis <input type="checkbox"/> New Primary Diagnosis	Month: ___ Day: ___ Year: _____	<input type="checkbox"/> Lung <input type="checkbox"/> Liver <input type="checkbox"/> Brain <input type="checkbox"/> Bone <input type="checkbox"/> Lymph Nodes <input type="checkbox"/> Other(Please Specify)		<input type="checkbox"/> Surgery <input type="checkbox"/> Pharmaceutical Therapy <input type="checkbox"/> Radiation Therapy <input type="checkbox"/> Other Treatment Type	<input type="checkbox"/> Complete Response <input type="checkbox"/> Partial Response <input type="checkbox"/> Treatment Stopped Due to Toxicity <input type="checkbox"/> Treatment Ongoing <input type="checkbox"/> Unknown
<input type="checkbox"/> Progression <input type="checkbox"/> Recurrence <input type="checkbox"/> Metastasis <input type="checkbox"/> New Primary Diagnosis	Month: ___ Day: ___ Year: _____	<input type="checkbox"/> Lung <input type="checkbox"/> Liver <input type="checkbox"/> Brain <input type="checkbox"/> Bone <input type="checkbox"/> Lymph Nodes <input type="checkbox"/> Other (Please Specify)		<input type="checkbox"/> Surgery <input type="checkbox"/> Pharmaceutical Therapy <input type="checkbox"/> Radiation Therapy <input type="checkbox"/> Other Treatment Type	<input type="checkbox"/> Complete Response <input type="checkbox"/> Partial Response <input type="checkbox"/> Treatment Stopped Due to Toxicity <input type="checkbox"/> Treatment Ongoing <input type="checkbox"/> Unknown
<input type="checkbox"/> Progression <input type="checkbox"/> Recurrence <input type="checkbox"/> Metastasis <input type="checkbox"/> New Primary Diagnosis	Month: ___ Day: ___ Year: _____	<input type="checkbox"/> Lung <input type="checkbox"/> Liver <input type="checkbox"/> Brain <input type="checkbox"/> Bone <input type="checkbox"/> Lymph Nodes <input type="checkbox"/> Other (Please Specify)		<input type="checkbox"/> Surgery <input type="checkbox"/> Pharmaceutical Therapy <input type="checkbox"/> Radiation Therapy <input type="checkbox"/> Other Treatment Type	<input type="checkbox"/> Complete Response <input type="checkbox"/> Partial Response <input type="checkbox"/> Treatment Stopped Due to Toxicity <input type="checkbox"/> Treatment Ongoing <input type="checkbox"/> Unknown
<input type="checkbox"/> Progression <input type="checkbox"/> Recurrence <input type="checkbox"/> Metastasis <input type="checkbox"/> New Primary	Month: ___ Day: ___ Year: _____	<input type="checkbox"/> Lung <input type="checkbox"/> Liver <input type="checkbox"/> Brain <input type="checkbox"/> Bone		<input type="checkbox"/> Surgery <input type="checkbox"/> Pharmaceutical Therapy <input type="checkbox"/> Radiation Therapy <input type="checkbox"/> Other Treatment Type	<input type="checkbox"/> Complete Response <input type="checkbox"/> Partial Response <input type="checkbox"/> Treatment Stopped Due to Toxicity

\*If time intervals are being provide din 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.

80	81	82	83	84	85
New Event Type	Date of New Event	Site of New Event	Other Site of New Event	New Event Treatment Type <i>(check all that apply)</i>	Treatment Outcome
Diagnosis		<input type="checkbox"/> Lymph Nodes <input type="checkbox"/> Other (Please Specify)			<input type="checkbox"/> Treatment Ongoing <input type="checkbox"/> Unknown
<input type="checkbox"/> Progression <input type="checkbox"/> Recurrence <input type="checkbox"/> Metastasis <input type="checkbox"/> New Primary Diagnosis	Month: ___ Day: ___ Year: _____	<input type="checkbox"/> Lung <input type="checkbox"/> Liver <input type="checkbox"/> Brain <input type="checkbox"/> Bone <input type="checkbox"/> Lymph Nodes <input type="checkbox"/> Other (Please Specify)		<input type="checkbox"/> Surgery <input type="checkbox"/> Pharmaceutical Therapy <input type="checkbox"/> Radiation Therapy <input type="checkbox"/> Other Treatment Type	<input type="checkbox"/> Complete Response <input type="checkbox"/> Partial Response <input type="checkbox"/> Treatment Stopped Due to Toxicity <input type="checkbox"/> Treatment Ongoing <input type="checkbox"/> Unknown

**Additional Survival Information**

87	88	89
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: _____	<input type="checkbox"/> Tumor Free at Follow-up <input type="checkbox"/> Never Tumor Free <input type="checkbox"/> New Tumor Event (remission/relapse) <input type="checkbox"/> Unknown	<input type="checkbox"/> Living <input type="checkbox"/> Deceased
Month: ___ Day: ___ Year: _____	<input type="checkbox"/> Tumor Free at Follow-up <input type="checkbox"/> Never Tumor Free <input type="checkbox"/> New Tumor Event (remission/relapse) <input type="checkbox"/> Unknown	<input type="checkbox"/> Living <input type="checkbox"/> Deceased
Month: ___ Day: ___ Year: _____	<input type="checkbox"/> Tumor Free at Follow-up <input type="checkbox"/> Never Tumor Free <input type="checkbox"/> New Tumor Event (remission/relapse) <input type="checkbox"/> Unknown	<input type="checkbox"/> Living <input type="checkbox"/> Deceased
Month: ___ Day: ___ Year: _____	<input type="checkbox"/> Tumor Free at Follow-up <input type="checkbox"/> Never Tumor Free <input type="checkbox"/> New Tumor Event (remission/relapse) <input type="checkbox"/> Unknown	<input type="checkbox"/> Living <input type="checkbox"/> Deceased
Month: ___	<input type="checkbox"/> Tumor Free at Follow-up <input type="checkbox"/> Never Tumor Free	<input type="checkbox"/> Living <input type="checkbox"/> Deceased

\*If time intervals are being provide din 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.

87	88	89
Date of Follow-up	Tumor Status	Vital Status
Day: __ __ Year: _____	<input type="checkbox"/> New Tumor Event (remission/relapse) <input type="checkbox"/> Unknown	
Month: __ __ Day: __ __ Year: _____	<input type="checkbox"/> Tumor Free at Follow-up <input type="checkbox"/> Never Tumor Free <input type="checkbox"/> New Tumor Event (remission/relapse) <input type="checkbox"/> Unknown	<input type="checkbox"/> Living <input type="checkbox"/> Deceased
Month: __ __ Day: __ __ Year: _____	<input type="checkbox"/> Tumor Free at Follow-up <input type="checkbox"/> Never Tumor Free <input type="checkbox"/> New Tumor Event (remission/relapse) <input type="checkbox"/> Unknown	<input type="checkbox"/> Living <input type="checkbox"/> Deceased



### 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.

**Note: Repeating interval information can be provided using OpenClinica or the spreadsheet version of this form.**

#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
4-ALT	3008233	Number of days from Date of Initial Pathologic Diagnosis to the <b>Date of Birth</b>		The number of days between the initial pathologic diagnosis and the date the patient was born.
23-ALT	5102380	Number of days from Date of Initial Pathologic Diagnosis to the <b>Date of Clinical Diagnosis</b>		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.
79-ALT	5102411	Number of days from Date of Initial Pathologic Diagnosis to the <b>Date the Agent used to Treat the Patient was First Administered</b>		The number of days between the initial pathologic diagnosis and the first date this agent was administered.
80-ALT	5102431	Number of days from Date of Initial Pathologic Diagnosis to the <b>Date the Agent used to Treat the Patient was Last Administered</b>		The number of days between the initial pathologic diagnosis and the last date this agent was administered.
81-ALT	3392464	Number of days from Date of Initial Pathologic Diagnosis to the <b>Date of New Tumor Event</b>		The number of days between the initial pathologic diagnosis and the date the new tumor was diagnosed.
86-ALT	5116090	Number of days from Date of Initial Pathologic Diagnosis to the <b>Date of Most Recent Last Contact</b>		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.
87-ALT	3008273	Number of days from Date of Initial Pathologic Diagnosis to the <b>Date of Follow-up</b>		The number of days between the initial pathologic diagnosis and the date when the TSS learned the patient's tumor status changed.
90-ALT	3165475	Number of days from Date of Initial Pathologic Diagnosis to the <b>Date of Death</b>		The number of days between the initial pathologic diagnosis and the date of death