

Enrollment: Ampulla of Vater

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Form Notes: An Enrollment Form should be completed for each HCMI case upon qualification notice from Leidos. All information provided on this form should include activity from the Date of Initial Pathologic Diagnosis to the most recent Date of Last Contact with the patient.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	☐ Initial pathologic diagnosis ☐ Sample procurement ☐ First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.
Patient Information				
4	Gender	☐ Male ☐ Female ☐ Unspecified	2200604	Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
5	Height	_____	649	Provide the patient's height, in centimeters.
6	Weight	_____	651	Provide the patient's weight, in kilograms.
7	Body mass index (BMI)	_____	2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
8	Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown ☐ Not reported	2192199	Provide the patient's race using the defined categories. **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 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. **Black or African American:** A person having origins in any of the black racial groups of Africa. **Native Hawaiian or other Pacific Islander:** A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island. **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
9	Ethnicity	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Not reported	2192217	Provide the patient's ethnicity using the defined categories. **Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. **Not Hispanic or Latino:** A person not meeting the definition of Hispanic or Latino.



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10	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.
11	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. ***Note: If the patient's age is greater than 32,872 days (90 years), please enter 32,872.***
12	Year of birth	_____	2896954	Provide the year of the patient's birth. If the patient was born prior to 1928, insert the date 1928.
13	Family history of cancer	☐ Same ☐ Different ☐ None ☐ Unknown	5832923	Has a first-degree relative of the patient been diagnosed with a cancer of the same or a different type?
14	Smoking history	☐ Lifelong non-smoker (<100 cigarettes smoked in a lifetime) ☐ Current smoker (includes daily and non-daily smokers) ☐ Current reformed smoker (duration not specified) ☐ Current reformed smoker for >15 years ☐ Current reformed smoker for ≤15 years	2181650	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories.
15	Metastasis at diagnosis assessment status	☐ Metastatic ☐ Non-metastatic (confirmed) ☐ Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor. ***Note: If metastatic at diagnosis, proceed to Question 16, otherwise, skip to Question 17.***
16	Metastatic site(s) at diagnosis	☐ Bone ☐ Brain ☐ Kidney ☐ Liver ☐ Lung ☐ Lymph node(s) distant ☐ Lymph node(s) regional ☐ Peritoneum ☐ Other (specify)	3029815	Indicate the site(s) of metastasis at the time of diagnosis of the primary tumor. ***Note: If the anatomic site of tumor tissue is not listed, proceed to Question 16a, otherwise, skip to Question 17.***
16a	Specify metastatic site(s)	_____	3128033	If the site of metastasis is not included on the provided list, specify the site of metastasis.
Biospecimen Information				
17	Tissue sample type(s) collected for HCMI for this case	☐ Normal tissue ☐ Primary tumor ☐ Metastatic ☐ Recurrent ☐ Other tissue	2006911	Please select all the tissue sample types submitted for HCMI with this case.
18	Number of NORMAL tissues biospecimens collected for HCMI for this case	_____	6584256	Please provide the number of normal tissue specimens obtained for HCMI for this case. ***Note: This number is expected to be 1.***
19	Number of PRIMARY cancer tissue biospecimens collected for HCMI model development for this case	_____	6584257	Please provide the number of primary tumor specimens obtained for HCMI for this case. ***Note: A single primary tumor biospecimen obtained that is portioned for both sequencing and model generation counts as 1 single primary tumor specimen. This number is expected to be 1.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
20	Number of METASTATIC/RECURRENT cancer tissue biospecimens collected for HCMI model development for this case	_____	6584258	Please provide the number of metastatic and/or recurrent cancer biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
21	Number of OTHER tissue biospecimens collected for HCMI model development for this case	_____	6584259	Please provide the number of pre-malignant, non-malignant, or dysplastic tissue biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
22	Total number of tissue biospecimens collected for HCMI for this case	_____	6584271	Please provide the total number of tissue biospecimens collected for HCMI for this case. ***Note: This number should be the sum of the normal, primary tumor, metastatic/ recurrent tumor, and other biospecimen counts above.***
Normal Control Information				
23	Normal tissue biospecimen ordinal	_____	6584264	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
24	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
25	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
26	Type of normal control	☐ Whole blood ☐ Buccal cells ☐ Buffy coat ☐ Lymphocytes ☐ Extracted DNA from blood ☐ Extracted DNA from saliva ☐ Extracted DNA from buccal cells ☐ Extracted DNA from normal tissue ☐ FFPE non-neoplastic tissue ☐ Non-neoplastic tissue	3081936	Indicate the type of normal control submitted for this case.
27	Anatomic site of normal tissue	☐ Duodenum ☐ Periampullary pancreas ☐ Other (specify) ☐ Not applicable	4132152	If non-neoplastic tissue was submitted as the normal control, select the anatomic site of the normal tissue. ***Note: If the anatomic site of normal tissue is not listed, proceed to Question 27a, otherwise, skip to Question 28.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
27a	Other anatomic site of normal tissue	_____	3288189	If non-neoplastic tissue, adjacent tissue, or normal tissue from another anatomic site was submitted as the normal control, provide the anatomic site of the normal tissue.
28	Distance from tumor to normal control tissue (if not blood)	☐ Adjacent (< or = 2cm) ☐ Distal (>2cm) ☐ Unknown ☐ Not applicable	3088708	Indicate the distance from the site of normal tumor collection to the primary tumor. ***Note: If normal tissue was not submitted, select 'Not applicable'.***
29	Normal tissue sample preservation method	☐ Cryopreserved ☐ OCT ☐ FFPE ☐ Snap frozen ☐ Frozen	5432521	Provide the method used to preserve the normal tissue sample collected for molecular characterization.
Primary Tumor Biospecimen Information				
30	ICD-10 code for primary tumor	☐ C24.1 ☐ Other (specify)	3226287	Provide the ICD-10 code for the primary tumor as used to generate the ID3 for this subject. ***Note: If the ICD-10 code is not listed, proceed to 30a, otherwise, skip to Question 31.***
30a	Other ICD-10 code for primary tumor	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.
31	Tumor Morphology	☐ 8013/3 ☐ 8156/3 ☐ 8310/3 ☐ 8020/3 ☐ 8240/3 ☐ 8480/3 ☐ 8035/3 ☐ 8241/3 ☐ 8490/3 ☐ 8041/3 ☐ 8244/3 ☐ 8560/3 ☐ 8070/3 ☐ 8246/3 ☐ 8576/3 ☐ 8140/3 ☐ 8249/3 ☐ Other (specify) ☐ 8144/3 ☐ 8260/3	3226275	Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor. ***Note: If the ICD-O-3 histology code of the primary tumor is not listed, proceed to Question 31a, otherwise, skip to Question 32.***
31a	Specify other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.
32	Tissue or organ of origin	☐ Ampulla of Vater ☐ Other (specify)	3427536	Using the patient's pathology/laboratory report, select the primary site of the disease. ***Note: If the primary site of the disease is not listed, proceed to Question 32a, otherwise skip to Question 33.***
32a	Other tissue or organ of origin	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord	3427536	If the primary site of the disease is not included on the previous list, provide the primary site of the disease.



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		☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva		
33	Histological Type	☐ Cancer of the Ampulla of Vater ☐ Other (specify)	3081932	Select the surgical pathology text description of the histological tumor type. ***Note: If the histological tumor type is not listed, proceed to Question 33a, otherwise, skip to Question 34.***
33a	Other histological type	_____	3294805	If the traditional surgical pathology text description of the histological tumor type is not included on the previous list, please specify the histological type.
34	Histological subtype	☐ Adenocarcinoma ☐ Adenocarcinoma with peculiar aspects ☐ Hepatoid carcinoma ☐ Medullary carcinoma ☐ Mixed adenoneuroendocrine carcinoma ☐ Moderately-differentiated neuroendocrine carcinoma ☐ Neuroendocrine carcinoma- large cell ☐ Neuroendocrine carcinoma- small cell ☐ Undifferentiated carcinoma ☐ Well-differentiated neuroendocrine carcinoma ☐ Other (specify) ☐ Unknown	3081934	Using the patient's pathology/laboratory report, select the histological subtype of the primary tumor. ***Note: If the histological subtype is not listed, proceed to Question 34a, otherwise, skip to Question 35.***
34a	Other histological subtype	_____	3124492	If the histological subtype for the primary tumor is not included in the provided list, specify the histological subtype.
35	If AVC histological subtype is adenocarcinoma, select the histotype	☐ Intestinal ☐ Mixed ☐ Pancreatico-biliary ☐ Unknown	6326080	If the histological subtype for the primary tumor is adenocarcinoma, specify the histotype.
36	If the AVC histological subtype is adenocarcinoma with peculiar aspects, select the subtype	☐ Clear cell ☐ Mucinous ☐ Signet ring ☐ Squamous differentiation ☐ Unknown	6326081	If the histological subtype for the primary tumor is adenocarcinoma with peculiar aspects, specify the subtype.
37	If well- or moderately-differentiated neuroendocrine tumor, specify the hormones released	_____	6326082	If the histological subtype for the primary tumor is well-differentiated or moderately-differentiated neuroendocrine tumor, please specify the hormones released. If the histological subtype is not well-or moderately-differentiated neuroendocrine tumor, please leave this section blank.



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38	Prior malignancy (of the same cancer type)	☐ Yes ☐ No ☐ Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
39	Prior malignancy (other cancer type)	☐ Yes ☐ No ☐ Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.
40	AJCC cancer staging edition	☐ 1st ☐ 4th ☐ 7th ☐ 2nd ☐ 5th ☐ 8th ☐ 3rd ☐ 6th	2722309	Select the AJCC staging handbook edition used to stage the patient's primary tumor.
41	Clinical stage group	☐ Stage 0 ☐ Stage III ☐ Stage IA ☐ Stage IIIA ☐ Stage IB ☐ Stage IIIB ☐ Stage IIA ☐ Stage IV ☐ Stage IIB	3440332	Using the patient's pathology/laboratory report, select the clinical stage group of the primary tumor as defined by the American Joint Committee on Cancer (AJCC).
42	AJCC pathologic spread: Primary tumor (pT)	☐ T0 ☐ T1b ☐ T3b ☐ Tis ☐ T2 ☐ T4 ☐ T1 ☐ T3 ☐ TX ☐ T1a ☐ T3a	3045435	Using the patient's pathology/laboratory report, select the code for the pathologic T (primary tumor) as defined by the American Joint Committee on Cancer (AJCC).
43	AJCC pathologic spread: Lymph nodes (pN)	☐ NX ☐ N0 ☐ N1 ☐ N2	3203106	Using the patient's pathology/laboratory report, select the code for the pathologic N (nodal) as defined by the American Joint Committee on Cancer (AJCC).
44	AJCC pathologic spread: Distant metastases (pM)	☐ M0 ☐ M1	3045439	Using the patient's pathology/laboratory report, select the code for the pathologic M (metastasis) as defined by the American Joint Committee on Cancer (AJCC).
45	Tumor stage (pathological)	☐ Stage 0 ☐ Stage III ☐ Stage IA ☐ Stage IIIA ☐ Stage IB ☐ Stage IIIB ☐ Stage IIA ☐ Stage IV ☐ Stage IIB	3065862	Using the patient's pathology/laboratory report, in conjunction with the patient's medical record, select the stage as defined by the American Joint Committee on Cancer (AJCC).
46	Tumor grade	☐ G1-Well differentiated ☐ G2-Moderately differentiated ☐ G3-Poorly differentiated ☐ GX-Unknown	2785839	Using the patient's pathology/laboratory report, select the grade of the primary tumor.
47	Tumor extension	☐ Carcinoma in situ/high-grade dysplasia ☐ Tumor limited to ampulla of Vater or sphincter of Oddi ☐ Tumor invades beyond sphincter of Oddi (perisphincteric invasion) ☐ Tumor invades into duodenal submucosa ☐ Tumor invades into muscularis propria of the duodenum ☐ Tumor directly invades pancreas up to 0.5 cm ☐ Tumor extends more than 0.5 cm into pancreas ☐ Tumor extends into peripancreatic soft tissues ☐ Tumor extends into periduodenal tissue ☐ Tumor extends into duodenal serosa ☐ Tumor invades other adjacent organs or structures other than pancreas (specify) ☐ Cannot be assessed	6326086	Select all options that represent the extent to which the Ampulla of Vater tumor has invaded through the wall of an organ into surrounding organs and/or adjacent tissues. ***Note: If the tumor invades into other adjacent organs, proceed to Question 47a, otherwise skip to Question 48.***



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47a	Tumor extension other structures	_____	64351	If the Ampulla of Vater tumor has invaded adjacent organs or structures other than the pancreas, please specify the organ(s).
48	Venous invasion present?	☐ Yes ☐ No ☐ Unknown	64358	Indicate whether venous invasion was present in the tumor specimen. ***Note: If venous invasion was identified in the tumor specimen, proceed to Question 49, otherwise skip to Question 50.***
49	Venous invasion type	☐ Extramural ☐ Intramural ☐ Unknown	6036344	Identify the location of vascular involvement for the tumor.
50	Lymphatic invasion present?	☐ Yes ☐ No ☐ Unknown	64171	Indicate if malignant cells are present in small or thin-walled vessels, suggesting lymphatic involvement.
51	Perineural invasion present?	☐ Yes ☐ No ☐ Unknown	64181	Indicate if perineural invasion or infiltration of tumor or cancer is present.
52	Number of positive lymph nodes	_____	89	Provide the number of lymph nodes involved with disease as determined by pathologic examination.
53	Number of lymph nodes examined	_____	3	Provide the number of lymph nodes removed and pathologically assessed for disease.
54	Margins of surgical resection	☐ R0 ☐ R1 ☐ R2 ☐ RX ☐ Not evaluated	2608702	Indicate the status of the tissue margins following surgical resection of the tumor submitted for HCMI.
Primary Tumor Sample Information				
55	Are you submitting a primary tumor tissue sample for this case?	☐ Yes ☐ No		***If yes, proceed to question 56.*** ***If submitting a metastatic/recurrent tumor sample, proceed to Question 84.***
56	Primary tumor biospecimen ordinal	_____	6584265	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number should be "1".***
57	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
58	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
59	Sample represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this primary tumor specimen represent the PRIMARY DIAGNOSIS for this Case ID3? ***Note: If no, continue to Question 60, otherwise, skip to Question 61.***
60	Specify the ICD-10 code	_____	3226287	Provide the ICD-10 code for the primary tumor used to generate the model submitted to HCMI.
61	Tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the tumor tissue sample collected for molecular characterization.
62	Anatomic Site of tumor from which Model was Derived	☐ Ampulla of Vater ☐ Bone ☐ Brain ☐ Kidney ☐ Liver ☐ Lung ☐ Lymph node ☐ Peritoneum ☐ Other (specify)	6033148	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI. ***Note: If the tissue or organ of origin is not listed, proceed to Question 62a. Otherwise, skip to Question 63.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
62a	Other anatomic site from which the tumor was obtained	_____	5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.
63	Method of cancer sample procurement	☐ Ampullectomy ☐ Pancreaticoduodenectomy ☐ Other (specify)	3103514	Provide the procedure performed to obtain the primary tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 63a, otherwise, skip to Question 64.***
63a	Specify the other method of tumor sample procurement	_____	2006730	Specify the procedure performed to obtain the primary tumor tissue, if not included in the previous list.
64	Number of days from index date to date of tumor sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the tumor tissue submitted for HCMI.
65	Tumor tissue type	☐ Primary ☐ Additional Primary ☐ NOS	3288124	Provide the primary tumor tissue type for this sample.
Primary Tumor Model Information				
66	Primary model biospecimen ordinal	_____	6594596	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number is expected to be "1".***
67	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
68	BPC submitter ID (if available)		6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
69	Model represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this MODEL represent the PRIMARY DIAGNOSIS for this Case ID3?
70	Model's primary tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the PRIMARY TUMOR TISSUE from which this model is derived.
71	Model's primary tumor biospecimen ordinal	_____	6584265	Enter the biospecimen ordinal of the PRIMARY TUMOR TISSUE from which this model is derived.
Treatment Information				
72	History of neoadjuvant treatment	☐ No ☐ Yes; radiation prior to resection ☐ Yes; pharmaceutical treatment prior to resection ☐ Yes; both radiation and pharmaceutical treatment prior to resection ☐ Unknown	3382737	Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment. ***Note: Pharmaceutical therapy is addressed in Questions 73-81. Radiation therapy is addressed in Questions 82-83.***
73	Neoadjuvant chemotherapy type	☐ Cytotoxic chemotherapy ☐ Hormonal ☐ Immunotherapy (cellular and immune checkpoint) ☐ Targeted therapy (small molecule inhibitors and targeted antibodies) ☐ Not applicable	5832928	Select all neoadjuvant chemotherapy types that were administered to the patient. ***Note: Cytotoxic chemotherapy is addressed in Questions 74-75. Immunotherapy is addressed in Questions 78-79. Targeted therapy is addressed in Questions 80-81.***
74	Neoadjuvant chemotherapeutic regimen	☐ 5-fluorouracil ☐ Capecitabine ☐ Cisplatin ☐ Gemcitabine ☐ Oxaliplatin ☐ Topotecan ☐ Other (specify) ☐ Chemotherapy not given	2853313	Select all chemotherapeutics used for neoadjuvant therapy. ***Note: If neoadjuvant chemotherapy was not given, skip to Question 76. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 74a, otherwise, skip to Question 75.***



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74a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapies administered.
75	Days to neoadjuvant chemotherapy treatment from index date	_____	5102411	Provide the number of days from index date to the date of treatment with neoadjuvant chemotherapy.
76	Hormone therapy	☐ Lanreotide ☐ Octreotide ☐ Other (specify)	6326083	Select the hormone therapy administered to the patient. ***Note: If the hormone therapy regimen is not listed, proceed to Question 76a, otherwise, skip to Question 77.***
76a	Other hormone therapy	_____	2405358	If the hormone therapy is not included in the provided list, specify hormone therapy administered.
77	Days to hormone therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with hormone therapy.
78	Immunotherapy	☐ Atezolizumab ☐ Nivolumab ☐ Avelumab ☐ Pembrolizumab ☐ Durvalumab ☐ Other (specify)	6326085	Select the immunotherapy administered to the patient. ***Note: If the immunotherapy regimen is not listed, proceed to Question 78a, otherwise, skip to Question 79.***
78a	Other immunotherapy name	_____	2953828	If the immunotherapy is not included in the provided list, specify immunotherapy administered.
79	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
80	Targeted Therapy	☐ Erlotinib ☐ Everolimus ☐ Other (specify)	6326084	Select the targeted therapy administered to the patient. ***Note: If the targeted therapy regimen is not listed, proceed to Question 80a, otherwise, skip to Question 81.***
80a	Specify targeted therapy	_____	4308476	Provide the name of the targeted therapy administered to the patient.
81	Days to targeted therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with targeted therapy.
82	Radiation therapy administered type	☐ 2D conventional ☐ Stereotactic Body RT ☐ 3D conformal ☐ Stereotactic Radiosurgery ☐ Brachytherapy HDR ☐ WBRT ☐ Brachytherapy LDR ☐ Other (specify) ☐ IMRT ☐ Unspecified ☐ Proton Beam ☐ Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. ***Note: If radiation therapy was not administered, proceed to Question 84. If the radiation therapy is not listed, proceed to Question 82a, otherwise, skip to Question 83.***
82a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
83	Days to radiation treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with radiation therapy.
Metastatic/Recurrent Tumor Biospecimen Information				
84	Are you submitting a metastatic/recurrent tumor tissue sample?	☐ Yes ☐ No		Indicate whether a metastatic/recurrent tumor biospecimen was collected for this ID3 case. ***Note: If yes, proceed to Question 85. If submitting an OTHER tissue sample, proceed to Question 145.***
85	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1", the second should be number "2", etc.***



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86	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
87	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
88	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
89	Number of days from index date to date of diagnosis of metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic/recurrent disease.
90	Method of metastatic/ recurrent cancer sample procurement	☐ Ampullectomy ☐ Pancreaticoduodenectomy ☐ Other (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 91a, otherwise, skip to Question 92.***
91a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
92	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
93	Metastatic/recurrent site	☐ Ampulla of Vater ☐ Bone ☐ Brain ☐ Kidney ☐ Liver ☐ Lung ☐ Lymph node(s) distant ☐ Lymph node(s) regional ☐ Peritoneum ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 93a, otherwise, skip to Question 94.***
93a	Other metastatic/ recurrent site	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.



Enrollment: Ampulla of Vater

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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		☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva		
94	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
95	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
96	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
97	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
98	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
99	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
100	Is the patient still receiving treatment?	_____	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
101	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
102	Tumor extension	☐ Carcinoma in situ/high-grade dysplasia ☐ Tumor limited to Ampulla of Vater or sphincter of Oddi ☐ Tumor invades beyond sphincter of Oddi (perisphincteric invasion) ☐ Tumor invades into duodenal submucosa ☐ Tumor invades into muscularis propria of the duodenum ☐ Tumor directly invades pancreas up to 0.5 cm ☐ Tumor extends more than 0.5 cm into pancreas ☐ Tumor extends into peripancreatic soft tissues ☐ Tumor extends into periduodenal tissue ☐ Tumor extends into duodenal serosa	6326086	Select all options that represent the extent to which the Ampulla of Vater tumor has invaded through the wall of an organ into surrounding organs and/or adjacent tissues. ***Note: If the tumor invades into other adjacent organs, proceed to Question 102a, otherwise skip to Question 103.***



Enrollment: Ampulla of Vater

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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		☐ Tumor invades other adjacent organs or structures other than pancreas (specify) ☐ Cannot be assessed		
102a	Tumor extension other structures	_____	64351	If the Ampulla of Vater tumor has invaded adjacent organs or structures other than the pancreas, please specify the organ(s).
103	Venous invasion present?	☐ Yes ☐ No ☐ Unknown	64358	Indicate whether venous invasion was present in the tumor specimen. ***Note: If venous invasion was identified in the tumor specimen, proceed to Question 104, otherwise skip to Question 105.***
104	Venous invasion type	☐ Extramural ☐ Intramural ☐ Unknown	6036344	Identify the location of vascular involvement for the tumor.
105	Lymphatic invasion present?	☐ Yes ☐ No ☐ Unknown	64171	Indicate if malignant cells are present in small or thin-walled vessels, suggesting lymphatic involvement.
106	Perineural invasion present?	☐ Yes ☐ No ☐ Unknown	64181	Indicate if perineural invasion or infiltration of tumor or cancer is present.
107	Number of positive lymph nodes	_____	89	Provide the number of lymph nodes involved with disease as determined by pathologic examination.
108	Number of lymph nodes examined	_____	3	Provide the number of lymph nodes removed and pathologically assessed for disease.
109	Margins of surgical resection	☐ R0 ☐ R1 ☐ R2 ☐ RX ☐ Not evaluated	2608702	Indicate the status of the tissue margins following surgical resection of the tumor submitted for HCMI.
Additional Metastatic/Recurrent Tumor Biospecimen Information (if applicable)				
110	Are you submitting an additional metastatic/ recurrent tumor tissue sample?	☐ Yes ☐ No		A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen. ***Note: If yes, proceed to Question 111, otherwise, skip to Question 135.***
111	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. The first biospecimen should be number "1," the second should be number "2," etc.
112	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
113	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
114	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
115	Number of days from index date to date of diagnosis of additional metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of additional metastatic/recurrent disease.



Enrollment: Ampulla of Vater

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
116	Method of metastatic/ recurrent cancer sample procurement	☐ Ampullectomy ☐ Pancreaticoduodenectomy ☐ Other (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 116a, otherwise, skip to Question 117.***
116a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
117	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
118	Metastatic/ recurrent site	☐ Ampulla of Vater ☐ Bone ☐ Brain ☐ Kidney ☐ Liver ☐ Lung ☐ Lymph node(s) distant ☐ Lymph node(s) regional ☐ Peritoneum ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 118a, otherwise, skip to Question 119.***
118a	Other metastatic/ recurrent site	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
119	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.



Enrollment: Ampulla of Vater

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
120	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
121	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
122	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
123	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
124	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
125	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
126	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
127	Tumor extension	☐ Carcinoma in situ/high-grade dysplasia ☐ Tumor limited to ampulla of Vater or sphincter of Oddi ☐ Tumor invades beyond sphincter of Oddi (perisphincteric invasion) ☐ Tumor invades into duodenal submucosa ☐ Tumor invades into muscularis propria of the duodenum ☐ Tumor directly invades pancreas up to 0.5 cm ☐ Tumor extends more than 0.5 cm into pancreas ☐ Tumor extends into peripancreatic soft tissues ☐ Tumor extends into periduodenal tissue ☐ Tumor extends into duodenal serosa ☐ Tumor invades other adjacent organs or structures other than pancreas (specify) ☐ Cannot be assessed	6326086	Select all options that represent the extent to which the Ampulla of Vater tumor has invaded through the wall of an organ into surrounding organs and/or adjacent tissues. ***Note: If the tumor invades into other adjacent organs, proceed to Question 127a, otherwise skip to Question 128.***
127a	Tumor extension other structures	_____	64351	If the Ampulla of Vater tumor has invaded adjacent organs or structures other than the pancreas, please specify the organ(s).
128	Venous invasion present?	☐ Yes ☐ No ☐ Unknown	64358	Indicate whether venous invasion was present in the tumor specimen. ***Note: If venous invasion was identified in the tumor specimen, proceed to Question 129, otherwise skip to Question 130.***



Enrollment: Ampulla of Vater

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
129	Venous invasion type	☐ Extramural ☐ Intramural ☐ Unknown	6036344	Identify the location of vascular involvement for the tumor.
130	Lymphatic invasion present?	☐ Yes ☐ No ☐ Unknown	64171	Indicate if malignant cells are present in small or thin-walled vessels, suggesting lymphatic involvement.
131	Perineural invasion present?	☐ Yes ☐ No ☐ Unknown	64181	Indicate if perineural invasion or infiltration of tumor or cancer is present.
132	Number of positive lymph nodes	_____	89	Provide the number of lymph nodes involved with disease as determined by pathologic examination.
133	Number of lymph nodes examined	_____	3	Provide the number of lymph nodes removed and pathologically assessed for disease.
134	Margins of surgical resection	☐ R0 ☐ R1 ☐ R2 ☐ RX ☐ Not evaluated	2608702	Indicate the status of the tissue margins following surgical resection of the tumor submitted for HCMI.
Metastatic/Recurrent Tumor Model Information				
135	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
136	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
137	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
138	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
139	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Additional Metastatic/Recurrent Biospecimen Tumor Model Information (if applicable)				
140	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
141	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
142	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
143	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
144	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.



Enrollment: Ampulla of Vater

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Other Biospecimen Information				
145	Are you submitting an OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an OTHER tissue sample (e.g. pre-malignant, non-malignant, or dysplastic tissue, etc.) was collected for HCMI for this case. ***Note: If yes, proceed to Question 146.***
146	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
147	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
148	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
149	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
150	Other method of cancer sample procurement	☐ Ampullectomy ☐ Pancreaticoduodenectomy ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 150a, otherwise, skip to Question 151.***
150a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
151	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
152	Tissue type	☐ Non-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 152a, otherwise, skip to Question 153.***
152a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
153	Anatomic site of OTHER tissue	☐ Ampulla of Vater ☐ Bone ☐ Brain ☐ Kidney ☐ Liver ☐ Lung ☐ Lymph node ☐ Peritoneum ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 153a, otherwise, skip to Question 154.***
153a	Specify anatomic site of OTHER tissue	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx	6584916	Specify the site of OTHER tissue, if not in the previous list.



Enrollment: Ampulla of Vater

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

		and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva		
154	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
155	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Additional OTHER biospecimen Information (if applicable)				
156	Are you submitting an additional OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an additional OTHER tissue sample (pre-malignant, non-malignant, or dysplastic tissue, etc.) is being submitted for HCMI for this case. ***Note: If yes, proceed to Question 157. If no, proceed to Question 167.***
157	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. The first biospecimen should be number "1," the second should be number "2," etc.
158	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
159	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
160	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
161	Other method of cancer sample procurement	☐ Ampullectomy ☐ Pancreaticoduodenectomy ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 161a, otherwise, skip to Question 162.***



Enrollment: Ampulla of Vater

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
161a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
162	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
163	Tissue type	☐ Non-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 163a, otherwise, skip to Question 164.***
163a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
164	Anatomic site of OTHER tissue	☐ Ampulla of Vater ☐ Bone ☐ Brain ☐ Kidney ☐ Liver ☐ Lung ☐ Lymph node ☐ Peritoneum ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 164a, otherwise, skip to Question 165.***
164a	Specify anatomic site of OTHER tissue	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	6584916	Specify the site of OTHER tissue, if not in the previous list.
165	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.



Enrollment: Ampulla of Vater

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Question Text
166	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Other Tissue Model Information				
167	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
168	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
169	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
170	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
171	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.
Additional Other Tissue Model Information (if applicable)				
172	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
173	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
174	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
175	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
176	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.



Enrollment: Brain

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Form Notes: An Enrollment Form should be completed for each HCMI case upon qualification notice from Leidos. All information provided on this form should include activity from the Date of Initial Pathologic Diagnosis to the most recent Date of Last Contact with the patient. This form should be used for the following Brain Cancers: Embryonal Tumor, Medulloblastoma, Diffuse Midline Glioma, and Lower Grade Glioma.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	☐ Initial pathologic diagnosis ☐ Sample procurement ☐ First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). ***Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.***
Patient Information				
4	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.
5	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. ***Note: If the patient's age is greater than 32,872 days (90 years), please enter 32,872.***
6	Gender	☐ Male ☐ Female ☐ Unspecified	2200604	Provide the patient's gender using the defined categories. ***Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.***
7	Height	_____	649	Provide the patient's height, in centimeters.
8	Weight	_____	651	Provide the patient's weight, in kilograms.
9	Body mass index (BMI)	_____	2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
10	Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown ☐ Not reported	2192199	Provide the patient's race using the defined categories. **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 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. **Black or African American:** A person having origins in any of the black racial groups of Africa. **Native Hawaiian or other Pacific Islander:** A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island. **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.



Enrollment: Brain

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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	Question Text	Data Entry Options	CDE ID	Instruction Text
11	Ethnicity	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Not reported	2192217	Provide the patient's ethnicity using the defined categories. **Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. **Not Hispanic or Latino:** A person not meeting the definition of Hispanic or Latino.
12	Year of birth	_____	2896954	Provide the year of the patient's birth. If the patient was born prior to 1928, insert the date 1928.
13	Family history of cancer	☐ Same ☐ Different ☐ None ☐ Unknown	5832923	Has a first-degree relative of the patient been diagnosed with a cancer of the same or a different type?
14	Smoking history	☐ Lifelong non-smoker (<100 cigarettes smoked in a lifetime) ☐ Current smoker (includes daily and non-daily smokers) ☐ Current reformed smoker (duration not specified) ☐ Current reformed smoker for >15 years ☐ Current reformed smoker for ≤15 years	2181650	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories.
15	Metastasis at diagnosis assessment status	☐ Metastatic ☐ Non-metastatic (confirmed) ☐ Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor.
16	Metastatic site(s) at diagnosis	☐ Ascites ☐ Bone ☐ Brain ☐ Bone marrow ☐ Cerebrospinal fluid (CSF) ☐ CNS ☐ Distant nodes ☐ Liver ☐ Lung ☐ Peritoneal nodes ☐ Pleural effusion ☐ Pleural nodules ☐ Regional node ☐ Soft tissue ☐ Spinal cord ☐ Other (specify)	3029815	Indicate the site(s) of metastasis at the time of diagnosis of the primary tumor. ***Note: If the anatomic site of tumor tissue is not listed, proceed to Question 16a, otherwise, skip to Question 17.***
16a	Specify metastatic site(s)	_____	3128033	If the site of metastasis is not included on the provided list, specify the site of metastasis.
Biospecimen Information				
17	Tissue sample type(s) collected for HCMI for this case	☐ Normal tissue ☐ Primary tumor ☐ Metastatic ☐ Recurrent ☐ Other tissue	2006911	Please select all the tissue sample types submitted for HCMI with this case.
18	Number of NORMAL tissues biospecimens collected for HCMI for this case	_____	6584256	Please provide the number of normal tissue specimens obtained for HCMI for this case. ***Note: This number is expected to be 1.***
19	Number of PRIMARY cancer tissue biospecimens collected for HCMI model development for this case	_____	6584257	Please provide the number of primary tumor specimens obtained for HCMI for this case. ***Note: A single primary tumor biospecimen obtained that is portioned for both sequencing and model generation counts as 1 single primary tumor specimen. This number is expected to be 1.***



Enrollment: Brain

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
20	Number of METASTATIC/ RECURRENT cancer tissue biospecimens collected for HCMI model development for this case	_____	6584258	Please provide the number of metastatic and/or recurrent cancer biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
21	Number of OTHER tissue biospecimens collected for HCMI model development for this case	_____	6584259	Please provide the number of pre-malignant, non-malignant, or dysplastic tissue biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
22	Total number of tissue biospecimens collected for HCMI for this case	_____	6584271	Please provide the total number of tissue biospecimens collected for HCMI for this case. ***Note: This number should be the sum of the normal, primary tumor, metastatic/recurrent tumor, and other biospecimen counts above.***
Normal Control Information				
23	Normal tissue biospecimen ordinal	_____	6584264	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
24	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
25	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
26	Type of normal control	☐ Whole blood ☐ Buccal cells ☐ Buffy coat ☐ Lymphocytes ☐ Extracted DNA from blood ☐ Extracted DNA from saliva ☐ Extracted DNA from buccal cells ☐ Extracted DNA from normal tissue (specify) ☐ FFPE non-neoplastic tissue (specify) ☐ Non-neoplastic tissue (specify)	3081936	Indicate the type of normal control submitted for this case. ***Note: if normal tissue or non-neoplastic tissue is selected, proceed to Question 26a, otherwise, skip to Question 27.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
26a	Other anatomic site of normal tissue	_____	3288189	If non-neoplastic tissue, adjacent tissue, or normal tissue from another anatomic site was submitted as the normal control, provide the anatomic site of the normal tissue. ***Proceed to Question 26b.***
26b	Distance from tumor to normal control tissue (if not blood)	☐ Adjacent (< or = 2cm) ☐ Distal (>2cm) ☐ Unknown ☐ Not applicable	3088708	Indicate the distance from the site of normal tumor collection to the primary tumor. ***Note: If normal tissue was not submitted, select 'Not applicable'.***
27	Normal tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the normal tissue sample collected for molecular characterization.
Primary Tumor Biospecimen Information				
28	ICD-10 code for primary tumor	☐ C71.0 ☐ C71.1 ☐ C71.3 ☐ C71.4 ☐ C71.5 ☐ C71.6 ☐ C71.7 ☐ C71.8 ☐ C71.8 ☐ C71.9 ☐ C71.9 ☐ C72.9 ☐ Other (specify)	3226287	Provide the ICD-10 code for the primary tumor as used to generate the ID3 for this subject. ***Note: If the ICD-10 code is not listed, proceed to Question 28a, otherwise, skip to Question 29***
28a	Other ICD-10 code for primary tumor	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.
29	Tumor Morphology	☐ 9380/3 ☐ 9382/3 ☐ 9392/3 ☐ 9400/3 ☐ 9401/3 ☐ 9421/1 ☐ 9424/3 ☐ 9451/3 ☐ 9470/3 ☐ 9471/3 ☐ 9474/3 ☐ 9490/3 ☐ 9500/3 ☐ 9501/3 ☐ 9502/3 ☐ 9505/3 ☐ 9508/3 ☐ 9550/3 ☐ Other (specify)	3226275	Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor. ***Note: If the ICD-O-3 histology code of the primary tumor is not listed, proceed to Question 29a, otherwise, skip to Question 30.***
29a	Specify other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.
30	Tissue or organ of origin	☐ Brain ☐ Spinal cord ☐ Other (specify)	3427536	Using the patient's pathology/laboratory report, select the primary site of the disease. ***Note: If the primary site of the disease is not listed, proceed to Question 30a, otherwise skip to Question 31.***
30a	Other tissue or organ of origin	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland	3427536	If the primary site of the disease is not included on the previous list, provide the primary site of the disease.



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		☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva		
Question	**Question Text**	**Data Entry Options**	**CDE ID**	**Instruction Text**
31	Histological Type	☐ Brain cancer ☐ Other (specify)	3081932	Select the surgical pathology text description of the histological tumor type. ***Note: If the histological tumor type is not listed, proceed to Question 31a, otherwise, skip to Question 32.***
31a	Other histological type	_____	3294805	If the traditional surgical pathology text description of the histological tumor type is not included on the previous list, please specify the histological type.
32	Brain cancer type	☐ Diffuse midline glioma (DIPG) ☐ Embryonal tumor ☐ Lower grade glioma ☐ Medulloblastoma		Select the brain tumor type.
33	Histological subtype	☐ Anaplastic astrocytoma ☐ Anaplastic ganglioglioma ☐ Anaplastic oligodendroglioma ☐ Anaplastic pleomorphic xanthoastrocytoma ☐ Classic medulloblastoma ☐ CNS atypical teratoid/rhabdoid tumor ☐ CNS ganglioneuroblastoma ☐ CNS neuroblastoma ☐ Desmoplastic/nodular medulloblastoma ☐ Embryonal tumor, NOS ☐ ETMR ☐ Indeterminate medulloblastoma ☐ Large cell/anaplastic medulloblastoma ☐ Lower grade glioma, NOS ☐ Medulloblastoma with extensive nodularity ☐ Medulloblastoma, NOS ☐ Medulloepithelioma ☐ Oligodendroglioma ☐ Pilocytic astrocytoma ☐ Other (specify)	3081934	Using the patient's pathology/laboratory report, select the histological subtype of the primary tumor. ***Note: If the histological subtype is not listed, proceed to Question 33a, otherwise, skip to Question 34.***
33a	Other histological subtype	_____	5946219	If the histological subtype for the primary tumor is not included in the provided list, specify the histological subtype.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
34	Prior malignancy (of the same cancer type)	☐ Yes ☐ No ☐ Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
35	Prior malignancy (other cancer type)	☐ Yes ☐ No ☐ Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.
36	WHO grade: lower grade glioma	☐ WHO Grade II ☐ WHO Grade III	2181858	Indicate grade of the lower grade glioma tumor according to the WHO guidelines.
37	WHO grade: diffuse midline glioma (DIPG), embryonal tumor, or medulloblastoma	☐ WHO Grade IV	2181858	Indicate grade of the diffuse midline glioma (DIPG), embryonal tumor, or medulloblastoma tumor according to the WHO guidelines.
38	Performance status score: Karnofsky score	☐ 100: Normal, no complaints ☐ 90: Able to carry out 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 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; Not Evaluated; Unknown	2003853	Indicate the score from the Karnofsky Performance status scale, representing the functional capabilities of a person.
39	Number of days from index date to the date initial score obtained for the Karnofsky performance status scale	_____	3479270	Provide the number of days from the index date to the date that the Karnofsky performance status assessment was performed.
40	Performance status score: Eastern Cooperative Oncology Group	☐ 0 Asymptomatic ☐ 1 Symptomatic, but fully ambulatory ☐ 2 Symptomatic, in bed less than 50% of the day ☐ 3 Symptomatic, in bed more than 50% of the day, but not bed-ridden ☐ 4 Bed-ridden ☐ 5 Dead ☐ Not evaluated ☐ Unknown	88	Indicate the ECOG functional performance status of the patient/participant.
41	Number of days from index date to the date initial score obtained for the ECOG performance status scale	_____	3479270	Provide the number of days from the index date to the date that the ECOG performance status assessment was performed.
42	Hereditary cancer predisposition syndrome	☐ Fanconi anemia ☐ Gorlin syndrome ☐ Li-Fraumeni syndrome ☐ Lynch syndrome ☐ Rubinstein-Taybi syndrome ☐ Turcot syndrome ☐ Unknown ☐ Not Applicable	6002201	Indicate any hereditary cancer predisposition syndromes identified in the patient.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Lower Grade Glioma Primary Tumor-specific Questions				
43	Laterality of site	☐ Right ☐ Left ☐ Midline	827	Provide the side of the body on which the lower grade glioma first developed.
44	Tumor site	☐ Supratentorial, frontal lobe ☐ Supratentorial, temporal lobe ☐ Supratentorial, parietal lobe ☐ Supratentorial, occipital lobe ☐ Posterior fossa, cerebellum ☐ Posterior fossa, brain stem ☐ Supratentorial, not otherwise specified	3139375	Select the anatomic location of the lower grade glioma within the brain.
45	Supratentorial localization	☐ Cerebral cortex ☐ Deep gray ☐ Spinal cord ☐ White matter ☐ Not listed on medical record	3133891	Select the location of the supratentorial tumor.
46	Symptom related to disease that presented first	☐ Headaches ☐ Mental status changes ☐ Motor/movement changes ☐ Seizures ☐ Sensory changes ☐ Visual changes ☐ Unknown	3133911	Select the patient's/participant's first presenting symptom of disease.
Primary Tumor Clinical Molecular Characterization				***Note: For Diffuse Midline Glioma (DIPG), continue to Question 47. For Lower Grade Glioma, proceed to Question 59. For Medulloblastoma, proceed to Question 66. Otherwise, proceed to Question 69.***
Diffuse Midline Glioma (DIPG) Primary Tumor Clinical Molecular Characterization				
47	Was H3 K27 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6062598	Indicate whether H3 K27 mutation analysis was performed.
48	Was a mutation in H3 K27 identified?	☐ Yes ☐ No	6002202	Indicate whether H3 K27 mutation was identified.
49	If H3 K27 mutation identified, in which variant was it found?	☐ H3.1 ☐ H3.3 ☐ Other	6002205	Select the H3 K27 mutation identified.
50	Was H3 K27M IHC performed?	☐ Yes ☐ No ☐ Unknown	6062409	Indicate whether H3 K27M was assessed by immunohistochemistry (IHC).
51	H3 K27M expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6002203	Indicate the expression of H3 K27M by immunohistochemistry (IHC).
52	Was IDH1/2 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6062597	Indicate whether mutation analysis of IDH1 or IDH2 was performed.
53	Was a mutation in IDH1/2 identified?	☐ Yes ☐ No	6002200	Indicate whether an IDH1 or IDH2 mutation was identified at testing.
54	If IDH1/2 mutation identified, which one?	☐ IDH1 R132H ☐ IDH1 R132C ☐ IDH1 R132S ☐ IDH1 R132G ☐ IDH1 R132L ☐ IDH2 R172W ☐ IDH2 R172K ☐ IDH2 R172M ☐ Other (specify)	6002206	Select the mutation identified in IDH1/2. ***Note: If the IDH1/2 mutation is not listed, proceed to Question 54a, otherwise, skip to Question 55.***
54a	Other IDH1/2 mutation	_____	6002207	If the mutation in IDH1/2 is not included in the provided list, specify the mutation in IDH1/2.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
55	What method was used to identify the IDH1/2 mutation?	☐ Cancer hotspot panel ☐ Next generation targeted sequencing ☐ Whole exome sequencing ☐ Not performed ☐ Other (specify)	6003729	Specify the method used to identify mutations. ***Note: If the method of mutation identification is not listed, proceed to Question 55a, otherwise, skip to Question 56.***
55a	Other mutation identification method	_____	6002204	If the mutation identification method is not included in the provided list, specify the method used to identify mutations.
56	Was IDH1 R132H IHC performed?	☐ Yes ☐ No ☐ Unknown	6062408	Indicate whether immunohistochemistry for IDH1 R132H was performed.
57	IDH1 R132H expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063674	Indicate the expression of IDH1 R132H per immunohistochemistry results.
58	MMR status	☐ Evidence of MMR mutation by sequencing ☐ Evidence of MMR protein loss by IHC ☐ MMR loss evidence hypermutation phenotype (>10mutations/Mb) ☐ No evidence of MMR alteration	6002208	Indicate the patient's Mismatch Repair (MMR) gene mutation status.
Lower Grade Glioma Primary Tumor Clinical Molecular Characterization				
59	Was IDH1/2 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6062597	Indicate whether mutation analysis of IDH1 or IDH2 was performed.
60	Was a mutation in IDH1/2 identified?	☐ Yes ☐ No	6002200	Indicate whether an IDH1 or IDH2 mutation was identified at testing.
61	If IDH1/2 mutation identified, which one?	☐ IDH1 R132H ☐ IDH1 R132C ☐ IDH1 R132S ☐ IDH1 R132G ☐ IDH1 R132L ☐ IDH2 R172W ☐ IDH2 R172K ☐ IDH2 R172M ☐ Other (specify)	6002206	Select the mutation identified in IDH1/2. ***Note: If the IDH1/2 mutation is not listed, proceed to Question 61a, otherwise, skip to Question 62.***
61a	Other IDH1/2 mutation	_____	6002207	If the mutation in IDH1/2 is not included in the provided list, specify the mutation in IDH1/2.
62	What method was used to identify the mutation?	☐ Next generation targeted sequencing ☐ Cancer hotspot panel ☐ Whole exome sequencing ☐ Not performed ☐ Other (specify)	6003729	Specify the method used to identify mutations. ***Note: If the method of mutation identification is not listed, proceed to Question 62a, otherwise, skip to Question 63.***
62a	Other mutation identification method	_____	6002204	If the mutation identification method is not included in the provided list, specify the method used to identify mutations.
63	Was IDH1 R132H IHC performed?	☐ Yes ☐ No ☐ Unknown	6062408	Indicate whether immunohistochemistry for IDH1 R132H was performed.
64	IDH1 R132H expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063674	Indicate the expression of IDH1 R132H per immunohistochemistry results.
65	MMR status	☐ Evidence of MMR mutation by sequencing ☐ Evidence of MMR protein loss by IHC ☐ MMR loss evidence hypermutation phenotype (>10mutations/Mb) ☐ No evidence of MMR alteration	6002208	Indicate the patient's Mismatch Repair (MMR) gene mutation status.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Medulloblastoma Primary Tumor Clinical Molecular Characterization				
66	MYCN gene amplification status	☐ Amplified ☐ Not amplified ☐ Not done ☐ Unknown	4616052	Indicate the amplification status of the MYCN gene.
67	Genetically defined subclass	☐ WNT-activated ☐ SHH-activated ☐ Non-WNT/non-SHH activated ☐ Not determined	6002209	Select the subclass of the medulloblastoma based on molecular features.
68	What are the markers that were used to determine WNT- or SHH- activation?	_____	6002210	Specify the genetic information used to determine the medulloblastoma subclass.
Primary Tumor Sample Information				
69	Are you submitting a primary tumor tissue sample for this case?	☐ Yes ☐ No		***If yes, proceed to question 70, otherwise, skip to Question 86.***
70	Primary tumor biospecimen ordinal	_____	6584265	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number should be "1".***
71	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
72	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
73	Sample represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this primary tumor specimen represent the PRIMARY DIAGNOSIS for this Case ID3? ***Note: If no, continue to Question 74. If yes, skip to Question 75.***
74	Specify the ICD-10 code	_____	3226287	Provide the ICD-10 code for the primary tumor used to generate the model submitted to HCMI.
75	Tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the tumor tissue sample collected for molecular characterization.
76	Anatomic site of tumor from which model was derived	☐ Ascites ☐ Bone ☐ Bone marrow ☐ Brain ☐ Cerebrospinal fluid (CSF) ☐ Liver ☐ Lung ☐ Lymph node ☐ Pleural effusion ☐ Pleural nodules ☐ Soft tissue ☐ Spinal Cord ☐ Other (specify) ☐ Unknown	4214629	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI. ***Note: If the tissue or organ of origin is not listed, proceed to Question 76a. Otherwise, skip to Question 77.***
76a	Other anatomic site from which the tumor was obtained	_____	5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.
77	Method of cancer sample procurement	☐ Biopsy ☐ Gross total resection ☐ Subtotal resection ☐ Other method (specify)	3103514	Provide the procedure performed to obtain the primary tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 77a, otherwise, skip to Question 78.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
77a	Specify the other method of tumor sample procurement	_____	2006730	Specify the procedure performed to obtain the primary tumor tissue, if not included in the previous list.
78	Number of days from index date to date of tumor sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the tumor tissue submitted for HCMI.
79	Tumor tissue type	☐ Primary ☐ Additional Primary ☐ NOS	3288124	Provide the primary tumor tissue type for this sample.
Primary Tumor Model Information				
80	Primary model biospecimen ordinal	_____	6594596	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number is expected to be "1".***
81	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
82	BPC submitter ID (if available)		6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
83	Model represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this MODEL represent the PRIMARY DIAGNOSIS for this Case ID3?
84	Model's primary tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the PRIMARY TUMOR TISSUE from which this model is derived.
85	Model's primary tumor biospecimen ordinal	_____	6584265	Enter the biospecimen ordinal of the PRIMARY TUMOR TISSUE from which this model is derived.
Treatment Information				
86	History of neoadjuvant treatment	☐ No ☐ Yes; radiation prior to resection ☐ Yes; pharmaceutical treatment prior to resection ☐ Yes; both radiation and pharmaceutical treatment prior to resection ☐ Unknown	3382737	Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment. ***Note: Radiation therapy is addressed in Questions 94-95. Pharmaceutical therapy is addressed in Questions 87-93.***
87	Neoadjuvant chemotherapy type	☐ Cytotoxic chemotherapy ☐ Immunotherapy (cellular and immune checkpoint) ☐ Targeted therapy (small molecule inhibitors and targeted antibodies) ☐ Not applicable	5832928	Select all neoadjuvant chemotherapy types that were administered to the patient. ***Note: Cytotoxic chemotherapy is addressed in Questions 88-89. Immunotherapy is addressed in Questions 90-91 Targeted therapy is addressed in Questions 92-93.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
88	Neoadjuvant chemotherapeutic regimen	☐ Bevacizumab ☐ Carboplatin ☐ Carmustine ☐ Cisplatin ☐ Cyclophosphamide ☐ Cytarabine ☐ Etoposide ☐ Hydroxyurea ☐ Irinotecan ☐ Lomustine ☐ Panobinostat ☐ Prednisone ☐ Procarbazine ☐ Temozolomide ☐ Vincristine ☐ Vorinostat ☐ Other (specify) ☐ Chemotherapy not given	2853313	Select all chemotherapeutics used for neoadjuvant therapy. ***Note: If neoadjuvant chemotherapy was not given, skip to Question 90. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 88a, otherwise, skip to Question 89.***
88a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapies administered.
89	Days to neoadjuvant chemotherapy treatment from index date	_____	5102411	Provide the number of days from index date to the date of treatment with neoadjuvant chemotherapy.
90	Specify immunotherapy	_____	2953828	Provide the name of the immunotherapy administered to the patient.
91	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
92	Specify targeted therapy	_____	4308476	Provide the name of the targeted therapy administered to the patient.
93	Days to targeted therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with targeted therapy.
94	Radiation therapy administered type	☐ 2D conventional ☐ 3D conformal ☐ Brachytherapy HDR ☐ Brachytherapy LDR ☐ IMRT ☐ Proton Beam ☐ Stereotactic Body RT ☐ Stereotactic Radiosurgery ☐ WBRT ☐ Other (specify) ☐ Unspecified ☐ Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. ***Note: If radiation therapy was not administered, proceed to Question 96. If the radiation therapy is not listed, proceed to Question 94a, otherwise, skip to Question 95.***
94a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
95	Days to radiation treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with radiation therapy.
Metastatic/Recurrent Tumor Biospecimen Information				
96	Are you submitting a metastatic/recurrent tumor tissue sample?	☐ Yes ☐ No		A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen. ***Note: If yes, proceed to Question 97. If no, proceed to Question 199.***



Enrollment: Brain

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
97	Metastatic tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1", the second should be number "2", etc.***
98	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
99	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
100	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
101	Number of days from index date to date of diagnosis of metastasis/recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic/recurrent disease.
102	Method of metastatic/ recurrent cancer sample procurement	☐ Biopsy ☐ Gross total resection ☐ Subtotal resection ☐ Other method (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 102a, otherwise, skip to Question 103.***
102a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
103	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
104	Metastatic/recurrent site	☐ Ascites ☐ Bone ☐ Bone marrow ☐ Brain ☐ Cerebrospinal fluid (CSF) ☐ CNS ☐ Distant nodes ☐ Liver ☐ Lung ☐ Peritoneal nodes ☐ Pleural effusion ☐ Pleural nodules ☐ Regional node ☐ Soft tissue ☐ Spinal Cord ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 104a, otherwise, skip to Question 105.***
104a	Other metastatic/ recurrent site	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.



Enrollment: Brain

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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		☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva		
105	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
106	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
107	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
108	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
109	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
110	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
111	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
112	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.



Enrollment: Brain

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
113	Performance status score: Karnofsky score	☐ 100: Normal, no complaints ☐ 90: Able to carry out 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 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; Not Evaluated; Unknown	2003853	Indicate the score from the Karnofsky Performance status scale, representing the functional capabilities of a person.
114	Number of days from index date to the date initial score obtained for the Karnofsky performance status scale	_____	3479270	Provide the number of days from the index date to the date that the Karnofsky performance status assessment was performed.
115	Performance status score: Eastern Cooperative Oncology Group (ECOG)	☐ 0 Asymptomatic ☐ 1 Symptomatic, but fully ambulatory ☐ 2 Symptomatic, in bed less than 50% of the day ☐ 3 Symptomatic, in bed more than 50% of the day, but not bed-ridden 4 Bed-ridden ☐ 5 Dead ☐ Not evaluated ☐ Unknown	88	Indicate the ECOG functional performance status of the patient/participant.
115a	Number of days from index date to the date score obtained for ECOG performance status	_____	3479270	Provide the number of days from the index date to the date that the ECOG performance status assessment was performed.
Lower Grade Glioma Metastatic/Recurrent Tumor-specific Questions				
116	Laterality of site	☐ Right ☐ Left ☐ Midline	827	Provide the side of the body on which the metastatic/recurrent lower grade glioma developed.
117	Tumor site	☐ Supratentorial, frontal lobe ☐ Supratentorial, temporal lobe ☐ Supratentorial, parietal lobe ☐ Supratentorial, occipital lobe ☐ Posterior fossa, cerebellum ☐ Posterior fossa, brain stem ☐ Supratentorial, not otherwise specified	3139375	Select the anatomic location of the lower grade glioma within the brain.
118	Supratentorial localization	☐ Cerebral cortex ☐ Deep gray ☐ Spinal cord ☐ White matter ☐ Not listed on medical record	3133891	Select the location of the supratentorial tumor.
119	Symptom related to disease that presented first	☐ Headaches ☐ Mental status changes ☐ Motor/movement changes ☐ Seizures ☐ Sensory changes ☐ Visual changes ☐ Unknown	3133911	Select the patient's/participant's first presenting symptom of disease.



Enrollment: Brain

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Metastatic/Recurrent Tumor Clinical Molecular Characterization				***Note: For metastatic/recurrent Diffuse Midline Glioma (DIPG), continue to question 120. For metastatic/recurrent Lower Grade Glioma, proceed to Question 132. For metastatic/recurrent Medulloblastoma, proceed to Question 139. Otherwise, proceed to Question 143.***
Diffuse Midline Glioma (DIPG) Metastatic/Recurrent Tumor Clinical Molecular Characterization				
120	Was H3 K27 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6062598	Indicate whether H3 K27 mutation analysis was performed.
121	Was a mutation in H3 K27 identified?	☐ Yes ☐ No	6002202	Indicate whether H3 K27 mutation was identified.
122	If H3 K27 mutation identified, in which variant was it found?	☐ H3.1 ☐ H3.3 ☐ Other	6002205	Select the H3 K27 mutation identified.
123	Was H3 K27M IHC performed?	☐ Yes ☐ No ☐ Unknown	6062409	Indicate whether H3 K27M was assessed by immunohistochemistry (IHC).
124	H3 K27M expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6002203	Indicate the expression of H3 K27M by immunohistochemistry (IHC).
125	Was IDH1/2 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6062597	Indicate whether mutation analysis of IDH1 or IDH2 was performed.
126	Was a mutation in IDH1/2 identified?	☐ Yes ☐ No		
127	If IDH1/2 mutation identified, which one?	☐ IDH1 R132H ☐ IDH1 R132C ☐ IDH1 R132S ☐ IDH1 R132G ☐ IDH1 R132L ☐ IDH2 R172W ☐ IDH2 R172K ☐ IDH2 R172M ☐ Other (specify)	6002206	***Note: If the IDH1/2 mutation is not listed, proceed to Question 127a, otherwise, skip to Question 128.***
127a	Other IDH1/2 mutation	_____	6002207	If the mutation in IDH1/2 is not included in the provided list, specify the mutation in IDH1/2.
128	What method was used to identify the IDH1/2 mutation?	☐ Cancer hotspot panel ☐ Next generation targeted sequencing ☐ Whole exome sequencing ☐ Not performed ☐ Other (specify)	6003729	Specify the method used to identify mutations. ***Note: If the method of mutation identification is not listed, proceed to Question 128a, otherwise, skip to Question 129.***
128a	Other mutation identification method	_____	6002204	If the mutation identification method is not included in the provided list, specify the method used to identify mutations.
129	Was IDH1 R132H IHC performed?	☐ Yes ☐ No ☐ Unknown	6062408	Indicate whether immunohistochemistry for IDH1 R132H was performed.
130	IDH1 R132H expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063674	Indicate the expression of IDH1 R132H per immunohistochemistry results.
131	MMR status	☐ Evidence of MMR mutation by sequencing ☐ Evidence of MMR protein loss by IHC ☐ MMR loss evidence hypermutation phenotype (>10mutations/Mb) ☐ No evidence of MMR alteration	6002208	Indicate the patient's Mismatch Repair (MMR) gene mutation status.
Lower Grade Glioma Metastatic/Recurrent Tumor Clinical Molecular Characterization				
132	Was IDH1/2 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6062597	Indicate whether mutation analysis of IDH1 or IDH2 was performed.



Enrollment: Brain

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
133	Was a mutation in IDH1/2 identified?	☐ Yes ☐ No	6002200	Indicate whether an IDH1 or IDH2 mutation was identified at testing.
134	If IDH1/2 mutation identified, which one?	☐ IDH1 R132H ☐ IDH1 R132C ☐ IDH1 R132S ☐ IDH1 R132G ☐ IDH1 R132L ☐ IDH2 R172W ☐ IDH2 R172K ☐ IDH2 R172M ☐ Other (specify)	6002206	Select the mutation identified in IDH1/2. ***Note: If the IDH1/2 mutation is not listed, proceed to Question 134a, otherwise, skip to Question 135.***
134a	Other IDH1/2 mutation	_____	6002207	If the mutation in IDH1/2 is not included in the provided list, specify the mutation in IDH1/2.
135	What method was used to identify the mutation?	☐ Next generation targeted sequencing ☐ Cancer hotspot panel ☐ Whole exome sequencing ☐ Not performed ☐ Other (specify)	6003729	Specify the method used to identify mutations. ***Note: If the method of mutation identification is not listed, proceed to Question 135a, otherwise, skip to Question 136.***
135a	Other mutation identification method	_____	6002204	If the mutation identification method is not included in the provided list, specify the method used to identify mutations.
136	Was IDH1 R132H IHC performed?	☐ Yes ☐ No ☐ Unknown	6062408	Indicate whether immunohistochemistry for IDH1 R132H was performed.
137	IDH1 R132H expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063674	Indicate the expression of IDH1 R132H per immunohistochemistry results.
138	MMR status	☐ Evidence of MMR mutation by sequencing ☐ Evidence of MMR protein loss by IHC ☐ MMR loss evidence hypermutation phenotype (>10mutations/Mb) ☐ No evidence of MMR alteration	6002208	Indicate the patient's Mismatch Repair (MMR) gene mutation status.
Medulloblastoma Metastatic/Recurrent Tumor Clinical Molecular Characterization				
139	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
140	MYCN gene amplification status	☐ Amplified ☐ Not amplified ☐ Not done ☐ Unknown	4616052	Indicate the amplification status of the MYCN gene.
141	Genetically defined subclass	☐ WNT-activated ☐ SHH-activated ☐ Non-WNT/non-SHH activated ☐ Not determined	6002209	Select the subclass of the medulloblastoma based on molecular features.
142	What are the markers that were used to determine WNT- or SHH- activation?	_____	6002210	Specify the genetic information used to determine the medulloblastoma subclass.



Enrollment: Brain

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Additional Metastatic/Recurrent Tumor Biospecimen Information (if applicable)				
143	Are you submitting an additional metastatic/ recurrent tumor tissue sample?	☐ Yes ☐ No		A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen. ***Note: If yes, proceed to Question 144, otherwise, skip to Question 189.***
144	Metastatic tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1", the second should be number "2", etc.***
145	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
146	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
147	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
148	Number of days from index date to date of diagnosis of metastasis/recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic/recurrent disease.
149	Method of metastatic/ recurrent cancer sample procurement	☐ Biopsy ☐ Gross total resection ☐ Subtotal resection ☐ Other method (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 149a, otherwise, skip to Question 150.***
149a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
150	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.



Enrollment: Brain

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
151	Metastatic/ recurrent site	☐ Ascites ☐ Bone ☐ Bone marrow ☐ Brain ☐ Cerebrospinal fluid (CSF) ☐ CNS ☐ Distant nodes ☐ Liver ☐ Lung ☐ Peritoneal nodes ☐ Pleural effusion ☐ Pleural nodules ☐ Regional node ☐ Soft tissue ☐ Spinal Cord ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 151a, otherwise, skip to Question 152.***
151a	Other metastatic/ recurrent site	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
152	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
153	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
154	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
155	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.



Enrollment: Brain

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
156	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
157	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
158	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
159	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
160	Performance status score: Karnofsky score	☐ 100: Normal, no complaints ☐ 90: Able to carry out 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 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; Not Evaluated; Unknown	2003853	Indicate the score from the Karnofsky Performance status scale, representing the functional capabilities of a person.
161	Number of days from index date to the date Karnofsky score obtained	_____	3479270	Provide the number of days from the index date to the date that the Karnofsky performance status assessment was performed.
162	Performance status score: Eastern Cooperative Oncology Group (ECOG)	☐ 0 Asymptomatic ☐ 1 Symptomatic, but fully ambulatory ☐ 2 Symptomatic, in bed less than 50% of the day ☐ 3 Symptomatic, in bed more than 50% of the day, but not bed-ridden ☐ 4 Bed-ridden ☐ 5 Dead ☐ Not evaluated ☐ Unknown	88	Indicate the ECOG functional performance status of the patient/participant.
162a	Number of days from index date to the date ECOG performance score obtained	_____	3479270	Provide the number of days from the index date to the date that the ECOG performance status assessment was performed.
Additional Lower Grade Glioma Metastatic/Recurrent Tumor-specific Questions				
163	Laterality of site	☐ Right ☐ Left ☐ Midline	827	Provide the side of the body on which the lower grade glioma first developed.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
164	Tumor site	☐ Supratentorial, frontal lobe ☐ Supratentorial, temporal lobe ☐ Supratentorial, parietal lobe ☐ Supratentorial, occipital lobe ☐ Posterior fossa, cerebellum ☐ Posterior fossa, brain stem ☐ Supratentorial, not otherwise specified	3139375	Select the anatomic location of the lower grade glioma within the brain.
165	Supratentorial localization	☐ Cerebral cortex ☐ Deep gray ☐ Spinal cord ☐ White matter ☐ Not listed on medical record	3133891	Select the location of the supratentorial tumor.
166	Symptom related to disease that presented first	☐ Headaches ☐ Mental status changes ☐ Motor/movement changes ☐ Seizures ☐ Sensory changes ☐ Visual changes ☐ Unknown	3133911	Select the patient's/participant's first presenting symptom of disease.
Additional Metastatic/Recurrent Tumor Clinical Molecular Characterization			***Note: For additional metastatic/recurrent Diffuse Midline Glioma (DIPG), continue to question 167. For additional metastatic/recurrent Lower Grade Glioma, proceed to Question 179. For additional metastatic/recurrent Medulloblastoma, proceed to Question 186. Otherwise, proceed to Question 190.***	
Diffuse Midline Glioma (DIPG) Additional Metastatic/Recurrent Tumor Clinical Molecular Characterization				
167	Was H3 K27 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6062598	Indicate whether H3 K27 mutation analysis was performed.
168	Was a mutation in H3 K27 identified?	☐ Yes ☐ No	6002202	Indicate whether H3 K27 mutation was identified.
169	If H3 K27 mutation identified, in which variant was it found?	☐ H3.1 ☐ H3.3 ☐ Other	6002205	Select the H3 K27 mutation identified.
170	Was H3 K27M IHC performed?	☐ Yes ☐ No ☐ Unknown	6062409	Indicate whether H3 K27M was assessed by immunohistochemistry (IHC).
171	H3 K27M expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6002203	Indicate the expression of H3 K27M by immunohistochemistry (IHC).
172	Was IDH1/2 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6062597	Indicate whether mutation analysis of IDH1 or IDH2 was performed.
173	Was a mutation in IDH1/2 identified?	☐ Yes ☐ No	6002200	Indicate whether an IDH1 or IDH2 mutation was identified at testing.
174	If IDH1/2 mutation identified, which one?	☐ IDH1 R132H ☐ IDH1 R132C ☐ IDH1 R132S ☐ IDH1 R132G ☐ IDH1 R132L ☐ IDH2 R172W ☐ IDH2 R172K ☐ IDH2 R172M ☐ Other (specify)	6002206	***Note: If the IDH1/2 mutation is not listed, proceed to Question 174a, otherwise, skip to Question 175.***
174a	Other IDH1/2 mutation	_____	6002207	If the mutation in IDH1/2 is not included in the provided list, specify the mutation in IDH1/2.
175	What method was used to identify the IDH1/2 mutation?	☐ Cancer hotspot panel ☐ Next generation targeted sequencing ☐ Whole exome sequencing ☐ Not performed ☐ Other (specify)	6003729	Specify the method used to identify mutations. ***Note: If the method of mutation identification is not listed, proceed to Question 175a, otherwise, skip to Question 176.***
175a	Other mutation identification method	_____	6002204	If the mutation identification method is not included in the provided list, specify the method used to identify mutations.



Enrollment: Brain

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
176	Was IDH1 R132H IHC performed?	☐ Yes ☐ No ☐ Unknown	6062408	Indicate whether immunohistochemistry for IDH1 R132H was performed.
177	IDH1 R132H expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063674	Indicate the expression of IDH1 R132H per immunohistochemistry results.
178	MMR status	☐ Evidence of MMR mutation by sequencing ☐ Evidence of MMR protein loss by IHC ☐ MMR loss evidence hypermutation phenotype (>10mutations/Mb) ☐ No evidence of MMR alteration	6002208	Indicate the patient's Mismatch Repair (MMR) gene mutation status.
Lower Grade Glioma Additional Metastatic/Recurrent Tumor Clinical Molecular Characterization				
179	Was IDH1/2 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6062597	Indicate whether mutation analysis of IDH1 or IDH2 was performed.
180	Was a mutation in IDH1/2 identified?	☐ Yes ☐ No	6002200	Indicate whether an IDH1 or IDH2 mutation was identified at testing.
181	If IDH1/2 mutation identified, which one?	☐ IDH1 R132H ☐ IDH1 R132G ☐ IDH2 R172K ☐ IDH1 R132C ☐ IDH1 R132L ☐ IDH2 R172M ☐ IDH1 R132S ☐ IDH2 R172W ☐ Other (specify)	6002206	Select the mutation identified in IDH1/2. ***Note: If the IDH1/2 mutation is not listed, proceed to Question 181a, otherwise, skip to Question 182.***
181a	Other IDH1/2 mutation	_____	6002207	If the mutation in IDH1/2 is not included in the provided list, specify the mutation in IDH1/2.
182	What method was used to identify the mutation?	☐ Next generation targeted sequencing ☐ Cancer hotspot panel ☐ Whole exome sequencing ☐ Not performed ☐ Other (specify)	6003729	Specify the method used to identify mutations. ***Note: If the method of mutation identification is not listed, proceed to Question 182a, otherwise, skip to Question 183.***
182a	Other mutation identification method	_____	6002204	If the mutation identification method is not included in the provided list, specify the method used to identify mutations.
183	Was IDH1 R132H IHC performed?	☐ Yes ☐ No ☐ Unknown	6062408	Indicate whether immunohistochemistry for IDH1 R132H was performed.
184	IDH1 R132H expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063674	Indicate the expression of IDH1 R132H per immunohistochemistry results.
185	MMR status	☐ Evidence of MMR mutation by sequencing ☐ Evidence of MMR protein loss by IHC ☐ MMR loss evidence hypermutation phenotype (>10mutations/Mb) ☐ No evidence of MMR alteration	6002208	Indicate the patient's Mismatch Repair (MMR) gene mutation status.
Medulloblastoma Additional Metastatic/Recurrent Tumor Clinical Molecular Characterization				
186	MYCN gene amplification status	☐ Amplified ☐ Not done ☐ Not amplified ☐ Unknown	4616052	Indicate the amplification status of the MYCN gene.
187	Genetically defined subclass	☐ WNT-activated ☐ SHH-activated ☐ Non-WNT/non-SHH activated ☐ Not determined	6002209	Select the subclass of the medulloblastoma based on molecular features.
188	What are the markers that were used to determine WNT- or SHH- activation?	_____	6002210	Specify the genetic information used to determine the medulloblastoma subclass.



Enrollment: Brain

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Metastatic/Recurrent Tumor Model Information				
189	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
190	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
191	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
192	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
193	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Additional Metastatic/Recurrent Tumor Model Information				
194	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
195	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
196	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
197	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
198	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Other Biospecimen Information				
199	Are you submitting an OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an OTHER tissue sample (e.g. pre-malignant, non-malignant, dysplastic tissue, etc.) was collected for HCMI for this case. ***Note: If yes, proceed to Question 200.***
200	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***



Enrollment: Brain

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
201	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
202	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
203	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
204	Method of OTHER tissue sample procurement	☐ Biopsy ☐ Other method (specify)	6587398	Indicate the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 204a, otherwise, skip to Question 205.***
204a	Other method of cancer sample procurement	_____	6587399	If the procedure performed to obtain the OTHER tissue is not included in the provided list, specify the procedure.
205	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
206	Tissue type	☐ Non-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 206a, otherwise, skip to Question 207.***
206a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
207	Anatomic site of OTHER tissue	☐ Ascites ☐ Bone ☐ Bone marrow ☐ Brain ☐ Cerebrospinal fluid (CSF) ☐ CNS ☐ Distant nodes ☐ Liver ☐ Lung ☐ Peritoneal nodes ☐ Pleural effusion ☐ Pleural nodules ☐ Regional node ☐ Soft tissue ☐ Spinal Cord ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 207a, otherwise, skip to Question 208.***
207a	Specify anatomic site of OTHER tissue	_____	6584916	If not included in the previous list, specify the site from which the OTHER tissue used to develop the model was derived.
208	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
209	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.



Enrollment: Brain

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Additional OTHER biospecimen Information (if applicable)				
210	Are you submitting an additional OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an OTHER tissue sample (e.g. pre-malignant, non-malignant, or dysplastic tissue, etc.) was collected for HCMI for this case. ***Note: If yes, proceed to Question 211, otherwise, skip to Question 221.***
211	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
212	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
213	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
214	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
215	Method of OTHER tissue sample procurement	☐ Biopsy ☐ Other method (specify)	6587398	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 215a, otherwise, skip to Question 216.***
215a	Other method of cancer sample procurement	_____	6587399	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
216	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
217	Tissue type	☐ Non-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 217a, otherwise, skip to Question 218.***
217a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
218	Anatomic site of OTHER tissue	☐ Ascites ☐ Bone ☐ Bone marrow ☐ Brain ☐ Cerebrospinal fluid (CSF) ☐ CNS ☐ Distant nodes ☐ Liver ☐ Lung ☐ Peritoneal nodes ☐ Pleural effusion ☐ Pleural nodules ☐ Regional node ☐ Soft tissue ☐ Spinal Cord ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 218a, otherwise, skip to Question 219.***



Enrollment: Brain

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
218a	Specify anatomic site of OTHER tissue	_____	6584916	If not included in the previous list, specify the site from which the OTHER tissue used to develop the model was derived.
219	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
220	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Other Tissue Model Information				
221	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
222	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
223	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
224	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
225	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.
Additional Other Tissue Model Information (if applicable)				
226	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
227	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
228	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
229	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
230	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.



Enrollment: Breast

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Form Notes: An Enrollment Form should be completed for each HCMI case upon qualification notice from Leidos. All information provided on this form should include activity from the Date of Initial Pathologic Diagnosis to the most recent Date of Last Contact with the patient.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	☐ Initial pathologic diagnosis ☐ Sample procurement ☐ First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.
Patient Information				
4	Gender	☐ Male ☐ Female ☐ Unspecified	2200604	Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
5	Height	_____	649	Provide the patient's height, in centimeters.
6	Weight	_____	651	Provide the patient's weight, in kilograms.
7	Body mass index (BMI)	_____	2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
8	Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown ☐ Not reported	2192199	Provide the patient's race using the defined categories. **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 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. **Black or African American:** A person having origins in any of the black racial groups of Africa. **Native Hawaiian or other Pacific Islander:** A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island. **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
9	Ethnicity	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Not reported	2192217	Provide the patient's ethnicity using the defined categories. **Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. **Not Hispanic or Latino:** A person not meeting the definition of Hispanic or Latino.



Enrollment: Breast

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
10	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.
11	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. ***Note: If the patient's age is greater than 32,872 days (90 years), please enter 32,872.***
12	Year of birth	_____	2896954	Provide the year of the patient's birth. If the patient was born prior to 1928, insert the date 1928.
13	Family history of cancer	☐ Same ☐ Different ☐ None ☐ Unknown	5832923	Has a first-degree relative of the patient been diagnosed with a cancer of the same or a different type?
14	Smoking history	☐ Lifelong non-smoker (<100 cigarettes smoked in a lifetime) ☐ Current smoker (includes daily and non-daily smokers) ☐ Current reformed smoker (duration not specified) ☐ Current reformed smoker for >15 years ☐ Current reformed smoker for ≤15 years	2181650	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories.
15	Metastasis at diagnosis assessment status	☐ Metastatic ☐ Non-metastatic (confirmed) ☐ Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor. ***Note: If metastatic at diagnosis, proceed to Question 16, otherwise, skip to Question 17.***
16	Metastatic site(s) at diagnosis	☐ Bone ☐ Brain ☐ Cutaneous ☐ Liver ☐ Lung ☐ Lymph node(s) axillary ☐ Lymph node(s) non-regional ☐ Other (specify)	3029815	Indicate the site(s) of metastasis at the time of diagnosis of the primary tumor. ***Note: If the anatomic site of tumor tissue is not listed, proceed to Question 16a, otherwise, skip to Question 17.***
16a	Specify metastatic site(s)	_____	3128033	If the site of metastasis is not included on the provided list, specify the site of metastasis.
Biospecimen Information				
17	Tissue sample type(s) collected for HCMI for this case	☐ Normal tissue ☐ Primary tumor ☐ Metastatic ☐ Recurrent ☐ Other tissue	2006911	Please select all the tissue sample types submitted for HCMI with this case.
18	Number of NORMAL tissues biospecimens collected for HCMI for this case	_____	6584256	Please provide the number of normal tissue specimens obtained for HCMI for this case. ***Note: This number is expected to be 1.***
19	Number of PRIMARY cancer tissue biospecimens collected for HCMI model development for this case	_____	6584257	Please provide the number of primary tumor specimens obtained for HCMI for this case. ***Note: A single primary tumor biospecimen obtained that is portioned for both sequencing and model generation counts as 1 single primary tumor specimen. This number is expected to be 1.***



Enrollment: Breast

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
20	Number of METASTATIC/RECURRENT cancer tissue biospecimens collected for HCMI model development for this case	_____	6584258	Please provide the number of metastatic and/or recurrent cancer biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
21	Number of OTHER tissue biospecimens collected for HCMI model development for this case	_____	6584259	Please provide the number of pre-malignant, non-malignant, or dysplastic tissue biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
22	Total number of tissue biospecimens collected for HCMI for this case	_____	6584271	Please provide the total number of tissue biospecimens collected for HCMI for this case. ***Note: This number should be the sum of the normal, primary tumor, metastatic/ recurrent tumor, and other biospecimen counts above.***
Normal Control Information				
23	Normal tissue biospecimen ordinal	_____	6584264	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
24	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
25	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
26	Type of normal control	☐ Whole blood ☐ Buccal cells ☐ Buffy coat ☐ Lymphocytes ☐ Extracted DNA from blood ☐ Extracted DNA from saliva ☐ Extracted DNA from buccal cells ☐ Extracted DNA from normal tissue ☐ FFPE non-neoplastic tissue ☐ Non-neoplastic tissue	3081936	Indicate the type of normal control submitted for this case.
27	Anatomic site of normal tissue	☐ Left breast ☐ Right breast ☐ Lymph node(s) ☐ Other (specify) ☐ Not applicable	4132152	If non-neoplastic tissue was submitted as the normal control, select the anatomic site of the normal tissue. ***Note: If the anatomic site of normal tissue is not listed, proceed to Question 27a, otherwise, skip to Question 28.***



Enrollment: Breast

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
27a	Other anatomic site of normal tissue	_____	3288189	If non-neoplastic tissue, adjacent tissue, or normal tissue from another anatomic site was submitted as the normal control, provide the anatomic site of the normal tissue.
28	Distance from tumor to normal control tissue (if not blood)	☐ Adjacent (< or = 2cm) ☐ Distal (>2cm) ☐ Unknown ☐ Not applicable	3088708	Indicate the distance from the site of normal tumor collection to the primary tumor. ***Note: If normal tissue was not submitted, select 'Not applicable'.***
29	Normal tissue sample preservation method	☐ Cryopreserved ☐ OCT ☐ FFPE ☐ Snap frozen ☐ Frozen	5432521	Provide the method used to preserve the normal tissue sample collected for molecular characterization.
Primary Tumor Biospecimen Information				
30	ICD-10 code for primary tumor	☐ C50.0 ☐ C50.4 ☐ C50.8 ☐ C50.1 ☐ C50.5 ☐ C50.9 ☐ C50.2 ☐ C50.6 ☐ Other (specify) ☐ C50.3	3226287	Provide the ICD-10 code for the primary tumor as used to generate the ID3 for this subject. ***Note: If the ICD-10 code is not listed, proceed to 30a, otherwise, skip to Question 31.***
30a	Other ICD-10 code for primary tumor	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.
31	Tumor Morphology	☐ 8022/3 ☐ 8410/3 ☐ 8525/3 ☐ 8032/3 ☐ 8430/3 ☐ 8530/3 ☐ 8035/3 ☐ 8480/3 ☐ 8540/3 ☐ 8041/3 ☐ 8500/3 ☐ 8550/3 ☐ 8070/3 ☐ 8502/3 ☐ 8570/3 ☐ 8200/3 ☐ 8503/3 ☐ 8571/3 ☐ 8201/3 ☐ 8504/3 ☐ 8572/3 ☐ 8211/3 ☐ 8507/3 ☐ 8574/3 ☐ 8246/3 ☐ 8509/3 ☐ 8575/3 ☐ 8290/3 ☐ 8510/3 ☐ 8982/3 ☐ 8314/3 ☐ 8513/3 ☐ 8983/3 ☐ 8315/3 ☐ 8520/3 ☐ Other (specify)	3226275	Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor. ***Note: If the ICD-O-3 histology code of the primary tumor is not listed, proceed to Question 31a, otherwise, skip to Question 32.***
31a	Specify other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.
32	Tissue or organ of origin	☐ Breast ☐ Other (specify)	3427536	Using the patient's pathology/laboratory report, select the primary site of the disease. ***Note: If the primary site of the disease is not listed, proceed to Question 32a, otherwise skip to Question 33.***
32a	Other tissue or organ of origin	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland	3427536	If the primary site of the disease is not included on the previous list, provide the primary site of the disease.



Enrollment: Breast

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

		☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva		
33	Histological Type	☐ Breast cancer ☐ Other (specify)	3081932	Select the surgical pathology text description of the histological tumor type. ***Note: If the histological tumor type is not listed, proceed to Question 33a, otherwise, skip to Question 34.***
33a	Other histological type	_____	3294805	If the traditional surgical pathology text description of the histological tumor type is not included on the previous list, please specify the histological type.
34	Histological subtype	☐ Infiltrating ductal carcinoma ☐ Infiltrating lobular carcinoma ☐ Mucinous carcinoma ☐ Medullary carcinoma ☐ Metaplastic ductal carcinoma ☐ Infiltrating carcinoma (NOS) ☐ Mixed histology (specify) ☐ Other (specify)	3081934	Using the patient's pathology/laboratory report, select the histological subtype of the primary tumor. ***Note: If the histological subtype is not listed, proceed to Question 34a, otherwise, skip to Question 35.***
34a	Other histological subtype	_____	3124492	If the histological subtype for the primary tumor is not included in the provided list, specify the histological subtype.
35	Prior malignancy (of the same cancer type)	☐ Yes ☐ No ☐ Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
36	Prior malignancy (other cancer type)	☐ Yes ☐ No ☐ Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.
37	AJCC cancer staging edition	☐ 1st ☐ 2nd ☐ 3rd ☐ 4th ☐ 5th ☐ 6th ☐ 7th ☐ 8th	2722309	Select the AJCC staging handbook edition used to stage the patient's primary tumor.
38	Clinical stage group	☐ Stage 0 ☐ Stage IA ☐ Stage IB ☐ Stage IIA ☐ Stage IIB ☐ Stage IIIA ☐ Stage IIIB ☐ Stage IIIC ☐ Stage IV	3440332	Using the patient's pathology/laboratory report, select the clinical stage group of the primary tumor as defined by the American Joint Committee on Cancer (AJCC).



Enrollment: Breast

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
39	AJCC pathologic spread: Primary tumor (pT)	☐ T0 ☐ Tis ☐ Tis (DCIS) ☐ Tis (LCIS) ☐ Tis (Paget's) ☐ T1 ☐ T1mi ☐ T1a ☐ T1b ☐ T1c ☐ T2 ☐ T3 ☐ T4 ☐ T4a ☐ T4b ☐ T4c ☐ T4d ☐ TX	3045435	Using the patient's pathology/laboratory report, select the code for the pathologic T (primary tumor) as defined by the American Joint Committee on Cancer (AJCC).
40	AJCC pathologic spread: Lymph nodes (pN)	☐ N0 ☐ N0 (i+) ☐ N0 (i-) ☐ N0 (mol+) ☐ N0 (mol-) ☐ N1 ☐ N1mi ☐ N1a ☐ N1b ☐ N1c ☐ N2 ☐ N2a ☐ N2b ☐ N3 ☐ N3a ☐ N3b ☐ N3c ☐ NX	3203106	Using the patient's pathology/laboratory report, select the code for the pathologic N (nodal) as defined by the American Joint Committee on Cancer (AJCC).
41	AJCC pathologic spread: Distant metastases (pM)	☐ M0 ☐ M1	3045439	Using the patient's pathology/laboratory report, select the code for the pathologic M (metastasis) as defined by the American Joint Committee on Cancer (AJCC).
42	Tumor stage (pathological)	☐ Stage 0 ☐ Stage IA ☐ Stage IB ☐ Stage IIA ☐ Stage IIB ☐ Stage IIIA ☐ Stage IIIB ☐ Stage IIIC ☐ Stage IV	3065862	Using the patient's pathology/laboratory report, in conjunction with the patient's medical record, select the stage as defined by the American Joint Committee on Cancer (AJCC).
43	Tumor grade	☐ G1-Well differentiated ☐ G2-Moderately differentiated ☐ G3-Poorly differentiated ☐ G4-Undifferentiated ☐ GB-Borderline histologic grade ☐ GX-Unknown	2785839	Using the patient's pathology/laboratory report, select the grade of the primary tumor.
44	Histopathologic grade	☐ Well differentiated ☐ Moderately differentiated ☐ Poorly differentiated ☐ Unknown	2186393	Using the patient's pathology/laboratory report, select the histopathologic grade of the primary tumor.
Prognostic/Predictive/Lifestyle Features for Primary Tumor Prognosis or Responsiveness to Treatment				
45	Menopause status	☐ Premenopausal ☐ Perimenopausal ☐ Postmenopausal ☐ Indeterminate or Unknown	2957270	Indicate the menopause status of the patient at the time of diagnosis.
46	Does the patient have bilateral malignancy (including DCIS)?	☐ Yes ☐ No ☐ Unknown	2177953	Indicate whether the patient has bilateral breast cancer (including ductal carcinoma in situ).
47	Micropapillary features	☐ Present ☐ Absent ☐ Unknown	6068784	Indicate whether micropapillary features were present in the primary tumor.
48	Did the patient receive hormonal therapy for the prevention of breast cancer?	☐ Yes ☐ No ☐ Unknown	3913290	Indicate whether the patient received hormonal therapy for the prevention of breast cancer.
49	Was Estrogen receptor (ER) IHC performed?	☐ Yes ☐ No ☐ Unknown	6062416	Indicate whether estrogen receptor (ER) expression was assessed by immunohistochemistry (IHC). ***Note: If ER IHC was not performed, skip to Question 51.***
50	ER Allred score	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8	2419219	Indicate the numeric Allred score (cell staining percentage plus intensity) for estrogen receptor.



Enrollment: Breast

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
51	Was Progesterone receptor (PR) IHC performed?	☐ Yes ☐ No ☐ Unknown	6062504	Indicate whether progesterone receptor (PR) expression was assessed by IHC. ***Note: If PR IHC was not performed, skip to Question 53.***
52	PR expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063673	Indicate the expression of progesterone receptor as assessed by immunohistochemistry (IHC).
53	Was HER2 IHC performed?	☐ Yes ☐ No ☐ Unknown	6063454	Indicate whether HER2 expression was assessed by immunohistochemistry (IHC). ***Note: If HER2 IHC was not performed, skip to Question 55.***
54	HER2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	2957563	Indicate the expression of HER2 as assessed by immunohistochemistry (IHC).
55	Was HER2 FISH/CISH performed?	☐ Yes ☐ No ☐ Unknown	6063447	Indicate whether HER2 was assessed by fluorescence in situ hybridization (FISH) or chromogenic in situ hybridization (CISH). ***Note: If HER2 FISH/CISH was not performed, skip to Question 57.***
56	HER2 status by FISH/CISH	☐ Amplified ☐ Not amplified ☐ Equivocal	2854089	Select the HER2 status as assessed by FISH/CISH.
57	HER2 copy number	_____	3133738	If HER2 copy number testing was performed, provide the average number of HER2 fluorescence in situ hybridization (FISH) signals for the patient's primary tumor. ***Note: If copy number analysis was not performed, skip to Question 61.***
58	Centromere 17 copy number	_____	3104295	If Centromere 17 copy number testing was performed, provide the average number of Centromere 17 fluorescence in situ hybridization (FISH) signals for the patient's primary tumor.
59	Number of cells counted for HER2 and Centromere 17 copy numbers	_____	3087902	Provide the total number of cells counted to assess HER2 and Centromere 17 copy numbers.
60	HER2/Centromere 17 signal ratio	_____	2497552	If HER2 and Centromere 17 copy number analyses were performed by FISH, provide the ratio of the outcomes of these tests.
61	Genomic test performed?	☐ Yes ☐ No ☐ Unknown	6069581	Indicate whether a genomic biomarker test (for example, Oncotype DX or MammaPrint) was performed. ***Note: If a genomic biomarker test was not performed, skip to Question 65.***
62	What genomic test was performed?	☐ Oncotype ☐ MammaPrint ☐ Other (specify)	6069582	Select the genomic test performed. ***Note: If the genomic test performed is Oncotype, proceed to Question 63. If the genomic test performed is MammaPrint, proceed to Question 64. If the genomic test performed is not listed, proceed to Questions 62a and b.***
62a	Other genomic test	_____	6069583	If the genomic test performed was not in the list, please provide the name of the test.
62b	If other genomic test was performed, provide the risk group	_____	6070422	Provide the risk group as assessed by a genomic test other than Oncotype or MammaPrint.



Enrollment: Breast

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
63	What is the patient's risk group according to the Oncotype recurrence score?	☐ Low ☐ Intermediate ☐ High	6069584	Indicate the risk group of the patient as determined by the Oncotype recurrence score.
64	What is the patient's risk group according to the MammaPrint test?	☐ Low ☐ High	6070421	Indicate the risk group of the patient as determined by the MammaPrint test.
Primary Tumor Sample Information				
65	Are you submitting a primary tumor tissue sample for this case?	☐ Yes ☐ No		***If yes, proceed to question 66.*** ***If submitting a metastatic/recurrent tumor sample, proceed to Question 94.***
66	Primary tumor biospecimen ordinal	_____	6584265	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number should be "1".***
67	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
68	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
69	Sample represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this primary tumor specimen represent the PRIMARY DIAGNOSIS for this Case ID3? ***Note: If no, continue to Question 70, otherwise, skip to Question 71.***
70	Specify the ICD-10 code	_____	3226287	Provide the ICD-10 code for the primary tumor used to generate the model submitted to HCMI.
71	Tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the tumor tissue sample collected for molecular characterization.
72	Anatomic Site of tumor from which Model was Derived	☐ Left breast ☐ Right breast ☐ Other (specify)	6033148	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI. ***Note: If the tissue or organ of origin is not listed, proceed to Question 72a. Otherwise, skip to Question 73.***
72a	Other anatomic site from which the tumor was obtained	_____	5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.
73	Method of cancer sample procurement	☐ Needle biopsy ☐ Lumpectomy ☐ Simple mastectomy ☐ Modified radical mastectomy ☐ Other (specify)	3103514	Provide the procedure performed to obtain the primary tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 73a, otherwise, skip to Question 74.***
73a	Specify the other method of tumor sample procurement	_____	2006730	Specify the procedure performed to obtain the primary tumor tissue, if not included in the previous list.
74	Number of days from index date to date of tumor sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the tumor tissue submitted for HCMI.
75	Tumor tissue type	☐ Primary ☐ Additional Primary ☐ NOS	3288124	Provide the primary tumor tissue type for this sample.



Enrollment: Breast

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Primary Tumor Model Information				
76	Primary model biospecimen ordinal	_____	6594596	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number is expected to be "1".***
77	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
78	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
79	Model represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this MODEL represent the PRIMARY DIAGNOSIS for this Case ID3?
80	Model's primary tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the PRIMARY TUMOR TISSUE from which this model is derived.
81	Model's primary tumor biospecimen ordinal	_____	6584265	Enter the biospecimen ordinal of the PRIMARY TUMOR TISSUE from which this model is derived.
Treatment Information				
82	History of neoadjuvant treatment	☐ No ☐ Yes; radiation prior to resection ☐ Yes; pharmaceutical treatment prior to resection ☐ Yes; both radiation and pharmaceutical treatment prior to resection ☐ Unknown	3382737	Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment. ***Note: Pharmaceutical therapy is addressed in Questions 83-91. Radiation therapy is addressed in Questions 92-93.***
83	Neoadjuvant chemotherapy type	☐ Cytotoxic chemotherapy ☐ Hormonal ☐ Immunotherapy (cellular and immune checkpoint) ☐ Targeted therapy (small molecule inhibitors and targeted antibodies) ☐ Not applicable	5832928	Select all neoadjuvant chemotherapy types that were administered to the patient. ***Note: Cytotoxic chemotherapy is addressed in Questions 84-85. Hormone therapy is addressed in Questions 86-87. Immunotherapy is addressed in Questions 88-89. Targeted therapy is addressed in Questions 90-91.***
84	Neoadjuvant chemotherapeutic regimen	☐ 5-fluorouracil ☐ Albumin-bound paclitaxel ☐ Capecitabine ☐ Carboplatin ☐ Cisplatin ☐ Docetaxel ☐ Epirubicin ☐ Eribulin ☐ Gemcitabine ☐ Ixabepilone ☐ Lapatinib ☐ Liposomal Doxorubicin ☐ Methotrexate ☐ Mitoxantrone ☐ Neratinib ☐ Paclitaxel ☐ T-DM1 ☐ Trastuzumab ☐ Vinorelbine ☐ Other (specify) ☐ Chemotherapy not given	2853313	Select all chemotherapeutics used for neoadjuvant therapy. ***Note: If neoadjuvant chemotherapy was not given, skip to Question 86. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 84a, otherwise, skip to Question 85.***
84a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapies administered.
85	Days to neoadjuvant chemotherapy treatment from index date	_____	5102411	Provide the number of days from index date to the date of treatment with neoadjuvant chemotherapy.



Enrollment: Breast

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
86	Hormone therapy	☐ Anastrazole ☐ Exemestane ☐ Fulvestrant ☐ Letrozole ☐ LHRH agonist ☐ Tamoxifen ☐ Toremifene ☐ Other (specify)	6326083	Select the hormone therapy administered to the patient. ***Note: If the hormone therapy regimen is not listed, proceed to Question 86a, otherwise, skip to Question 87.***
86a	Other hormone therapy	_____	2405358	If the hormone therapy is not included in the provided list, specify hormone therapy administered.
87	Days to hormone therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with hormone therapy.
88	Immunotherapy	_____	2953828	If the immunotherapy is not included in the provided list, specify immunotherapy administered.
89	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
90	Targeted Therapy	☐ Ado-trastuzumab emtansine ☐ Everolimus ☐ Lapatinib ☐ Palbociclib ☐ Pertuzumab ☐ Ribociclib ☐ Trastuzumab ☐ Other (specify)	6326084	Select the targeted therapy administered to the patient. ***Note: If the targeted therapy regimen is not listed, proceed to Question 90a, otherwise, skip to Question 91.***
90a	Specify targeted therapy	_____	4308476	Provide the name of the targeted therapy administered to the patient.
91	Days to targeted therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with targeted therapy.
92	Radiation therapy administered type	☐ 2D conventional ☐ 3D conformal ☐ Brachytherapy HDR ☐ Brachytherapy LDR ☐ IMRT ☐ Proton Beam ☐ Stereotactic Body RT ☐ Stereotactic Radiosurgery ☐ WBRT ☐ Other (specify) ☐ Unspecified ☐ Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. ***Note: If radiation therapy was not administered, proceed to Question 94. If the radiation therapy is not listed, proceed to Question 92a, otherwise, skip to Question 93.***
92a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
93	Days to radiation treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with radiation therapy.
Metastatic/Recurrent Tumor Biospecimen Information				
94	Are you submitting a metastatic/recurrent tumor tissue sample?	☐ Yes ☐ No		Indicate whether a metastatic/recurrent tumor biospecimen was collected for this ID3 case. ***Note: If yes, proceed to Question 95. If submitting an OTHER tissue sample, proceed to Question 182.***
95	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1", the second should be number "2", etc.***
96	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.



Enrollment: Breast

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
97	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
98	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
99	Number of days from index date to date of diagnosis of metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic/recurrent disease.
100	Method of metastatic/ recurrent cancer sample procurement	☐ Needle biopsy ☐ Lumpectomy ☐ Simple mastectomy ☐ Modified radical mastectomy ☐ Other (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 100a, otherwise, skip to Question 101.***
100a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
101	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
102	Metastatic/recurrent site	☐ Left breast ☐ Right breast ☐ Bone ☐ Brain ☐ Cutaneous ☐ Liver ☐ Lung ☐ Lymph node(s) axillary ☐ Lymph node(s) non-regional ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 102a, otherwise, skip to Question 103.***
102a	Other metastatic/ recurrent site	_____	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
103	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
104	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
105	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
106	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
107	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.



Enrollment: Breast

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
108	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
109	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
110	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
111	Tumor grade	☐ G1-Well differentiated ☐ G2-Moderately differentiated ☐ G3-Poorly differentiated ☐ G4-Undifferentiated ☐ GB-Borderline histologic grade ☐ GX-Unknown	2785839	Using the patient's pathology/laboratory report, select the grade of the primary tumor.
112	Histopathologic grade	☐ Well differentiated ☐ Moderately differentiated ☐ Poorly differentiated ☐ Unknown	2186393	Using the patient's pathology/laboratory report, select the histopathologic grade of the primary tumor.
Prognostic/Predictive/Lifestyle Features for Metastatic/Recurrent Tumor Prognosis or Responsiveness to Treatment				
113	Menopause status	☐ Premenopausal ☐ Perimenopausal ☐ Postmenopausal ☐ Indeterminate or Unknown	2957270	Indicate the menopause status of the patient at the time of diagnosis.
114	Does the patient have bilateral malignancy (including DCIS)?	☐ Yes ☐ No ☐ Unknown	2177953	Indicate whether the patient has bilateral breast cancer (including ductal carcinoma in situ).
115	Micropapillary features	☐ Present ☐ Absent ☐ Unknown	6068784	Indicate whether micropapillary features were present in the primary tumor.
116	Did the patient receive hormonal therapy for the prevention of breast cancer?	☐ Yes ☐ No ☐ Unknown	3913290	Indicate whether the patient received hormonal therapy for the prevention of breast cancer.
117	Was Estrogen receptor (ER) IHC performed?	☐ Yes ☐ No ☐ Unknown	6062416	Indicate whether estrogen receptor (ER) expression was assessed by immunohistochemistry (IHC). ***Note: If ER IHC was not performed, skip to Question 119.***
118	ER Allred score	☐ 0 ☐ 3 ☐ 6 ☐ 1 ☐ 4 ☐ 7 ☐ 2 ☐ 5 ☐ 8	2419219	Indicate the numeric Allred score (cell staining percentage plus intensity) for estrogen receptor.
119	Was Progesterone receptor (PR) IHC performed?	☐ Yes ☐ No ☐ Unknown	6062504	Indicate whether progesterone receptor (PR) expression was assessed by IHC. ***Note: If PR IHC was not performed, skip to Question 121.***
120	PR expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063673	Indicate the expression of progesterone receptor as assessed by immunohistochemistry (IHC).
121	Was HER2 IHC performed?	☐ Yes ☐ No ☐ Unknown	6063454	Indicate whether HER2 expression was assessed by immunohistochemistry (IHC). ***Note: If HER2 IHC was not performed, skip to Question 123.***
122	HER2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	2957563	Indicate the expression of HER2 as assessed by immunohistochemistry (IHC).



Enrollment: Breast

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
123	Was HER2 FISH/CISH performed?	☐ Yes ☐ No ☐ Unknown	6063447	Indicate whether HER2 was assessed by fluorescence in situ hybridization (FISH) or chromogenic in situ hybridization (CISH). ***Note: If HER2 FISH/CISH was not performed, skip to Question 125.***
124	HER2 status by FISH/CISH	☐ Amplified ☐ Not amplified ☐ Equivocal	2854089	Select the HER2 status as assessed by FISH/CISH.
125	HER2 copy number	_____	3133738	If HER2 copy number testing was performed, provide the average number of HER2 fluorescence in situ hybridization (FISH) signals for the patient's primary tumor. ***Note: If copy number analysis was not performed, skip to Question 129.***
126	Centromere 17 copy number	_____	3104295	If Centromere 17 copy number testing was performed, provide the average number of Centromere 17 fluorescence in situ hybridization (FISH) signals for the patient's primary tumor.
127	Number of cells counted for HER2 and Centromere 17 copy numbers	_____	3087902	Provide the total number of cells counted to assess HER2 and Centromere 17 copy numbers.
128	HER2/Centromere 17 signal ratio	_____	2497552	If HER2 and Centromere 17 copy number analyses were performed by FISH, provide the ratio of the outcomes of these tests.
129	Genomic test performed?	☐ Yes ☐ No ☐ Unknown	6069581	Indicate whether a genomic biomarker test (for example, Oncotype DX or MammaPrint) was performed. ***Note: If a genomic biomarker test was not performed, skip to Question 133.***
130	What genomic test was performed?	☐ Oncotype ☐ MammaPrint ☐ Other (specify)	6069582	Select the genomic test performed. ***Note: If the genomic test performed is Oncotype, proceed to Question 131. If the genomic test performed is MammaPrint, proceed to Question 132. If the genomic test performed is not listed, proceed to Questions 130a and b.***
130a	Other genomic test	_____	6069583	If the genomic test performed was not in the list, please provide the name of the test.
130b	If other genomic test was performed, provide the risk group	_____	6070422	Provide the risk group as assessed by a genomic test other than Oncotype or MammaPrint.
131	What is the patient's risk group according to the Oncotype recurrence score?	☐ Low ☐ Intermediate ☐ High	6069584	Indicate the risk group of the patient as determined by the Oncotype recurrence score.
132	What is the patient's risk group according to the MammaPrint test?	☐ Low ☐ High	6070421	Indicate the risk group of the patient as determined by the MammaPrint test.
Additional Metastatic/Recurrent Tumor Biospecimen Information (if applicable)				
133	Are you submitting an additional metastatic/ recurrent tumor tissue sample?	☐ Yes ☐ No		A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen. ***Note: If yes, proceed to Question 134, otherwise, skip to Question 172.***



Enrollment: Breast

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
134	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. The first biospecimen should be number "1," the second should be number "2," etc.
135	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
136	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
137	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
138	Number of days from index date to date of diagnosis of additional metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of additional metastatic/recurrent disease.
139	Method of metastatic/ recurrent cancer sample procurement	☐ Needle biopsy ☐ Lumpectomy ☐ Simple mastectomy ☐ Modified radical mastectomy ☐ Other (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 139a, otherwise, skip to Question 140.***
139a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
140	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
141	Metastatic/ recurrent site	☐ Left breast ☐ Right breast ☐ Bone ☐ Brain ☐ Cutaneous ☐ Liver ☐ Lung ☐ Lymph node(s) axillary ☐ Lymph node(s) non-regional ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 141a, otherwise, skip to Question 142.***
141a	Other metastatic/ recurrent site	_____	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
142	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
143	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
144	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
145	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.



Enrollment: Breast

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
146	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
147	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
148	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
149	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
Prognostic/Predictive/Lifestyle Features for Additional Metastatic/Recurrent Tumor Prognosis or Responsiveness to Treatment				
150	Tumor grade	☐ G1-Well differentiated ☐ G2-Moderately differentiated ☐ G3-Poorly differentiated ☐ G4-Undifferentiated ☐ GB-Borderline histologic grade ☐ GX-Unknown	2785839	Using the patient's pathology/laboratory report, select the grade of the primary tumor.
151	Histopathologic grade	☐ Well differentiated ☐ Moderately differentiated ☐ Poorly differentiated ☐ Unknown	2186393	Using the patient's pathology/laboratory report, select the histopathologic grade of the primary tumor.
152	Menopause status	☐ Premenopausal ☐ Perimenopausal ☐ Postmenopausal ☐ Indeterminate or Unknown	2957270	Indicate the menopause status of the patient at the time of diagnosis.
153	Does the patient have bilateral malignancy (including DCIS)?	☐ Yes ☐ No ☐ Unknown	2177953	Indicate whether the patient has bilateral breast cancer (including ductal carcinoma in situ).
154	Micropapillary features	☐ Present ☐ Absent ☐ Unknown	6068784	Indicate whether micropapillary features were present in the primary tumor.
155	Did the patient receive hormonal therapy for the prevention of breast cancer?	☐ Yes ☐ No ☐ Unknown	3913290	Indicate whether the patient received hormonal therapy for the prevention of breast cancer.
156	Was Estrogen receptor (ER) IHC performed?	☐ Yes ☐ No ☐ Unknown	6062416	Indicate whether estrogen receptor (ER) expression was assessed by immunohistochemistry (IHC). ***Note: If ER IHC was not performed, skip to Question 158.***
157	ER Allred score	☐ 0 ☐ 3 ☐ 6 ☐ 1 ☐ 4 ☐ 7 ☐ 2 ☐ 5 ☐ 8	2419219	Indicate the numeric Allred score (cell staining percentage plus intensity) for estrogen receptor.
158	Was Progesterone receptor (PR) IHC performed?	☐ Yes ☐ No ☐ Unknown	6062504	Indicate whether progesterone receptor (PR) expression was assessed by IHC. ***Note: If PR IHC was not performed, skip to Question 160.***
159	PR expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063673	Indicate the expression of progesterone receptor as assessed by immunohistochemistry (IHC).
160	Was HER2 IHC performed?	☐ Yes ☐ No ☐ Unknown	6063454	Indicate whether HER2 expression was assessed by immunohistochemistry (IHC). ***Note: If HER2 IHC was not performed, skip to Question 162.***



Enrollment: Breast

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
161	HER2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	2957563	Indicate the expression of HER2 as assessed by immunohistochemistry (IHC).
162	Was HER2 FISH/CISH performed?	☐ Yes ☐ No ☐ Unknown	6063447	Indicate whether HER2 was assessed by fluorescence in situ hybridization (FISH) or chromogenic in situ hybridization (CISH). ***Note: If HER2 FISH/CISH was not performed, skip to Question 164.***
163	HER2 status by FISH/CISH	☐ Amplified ☐ Not amplified ☐ Equivocal	2854089	Select the HER2 status as assessed by FISH/CISH.
164	HER2 copy number	_____	3133738	If HER2 copy number testing was performed, provide the average number of HER2 fluorescence in situ hybridization (FISH) signals for the patient's primary tumor. ***Note: If copy number analysis was not performed, skip to Question 168.***
165	Centromere 17 copy number	_____	3104295	If Centromere 17 copy number testing was performed, provide the average number of Centromere 17 fluorescence in situ hybridization (FISH) signals for the patient's primary tumor.
166	Number of cells counted for HER2 and Centromere 17 copy numbers	_____	3087902	Provide the total number of cells counted to assess HER2 and Centromere 17 copy numbers.
167	HER2/Centromere 17 signal ratio	_____	2497552	If HER2 and Centromere 17 copy number analyses were performed by FISH, provide the ratio of the outcomes of these tests.
168	Genomic test performed?	☐ Yes ☐ No ☐ Unknown	6069581	Indicate whether a genomic biomarker test (for example, Oncotype DX or MammaPrint) was performed. ***Note: If a genomic biomarker test was not performed, skip to Question 172.***
169	What genomic test was performed?	☐ Oncotype ☐ MammaPrint ☐ Other (specify)	6069582	Select the genomic test performed. ***Note: If the genomic test performed is Oncotype, proceed to Question 170. If the genomic test performed is MammaPrint, proceed to Question 171. If the genomic test performed is not listed, proceed to Questions 169a and b.***
169a	Other genomic test	_____	6069583	If the genomic test performed was not in the list, please provide the name of the test.
169b	If other genomic test was performed, provide the risk group	_____	6070422	Provide the risk group as assessed by a genomic test other than Oncotype or MammaPrint.
170	What is the patient's risk group according to the Oncotype recurrence score?	☐ Low ☐ Intermediate ☐ High	6069584	Indicate the risk group of the patient as determined by the Oncotype recurrence score.
171	What is the patient's risk group according to the MammaPrint test?	☐ Low ☐ High	6070421	Indicate the risk group of the patient as determined by the MammaPrint test.
Metastatic/Recurrent Tumor Model Information				
172	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***



Enrollment: Breast

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
173	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
174	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
175	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
176	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Additional Metastatic/Recurrent Biospecimen Tumor Model Information (if applicable)				
177	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
178	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
179	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
180	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
181	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Other Biospecimen Information				
182	Are you submitting an OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an OTHER tissue sample (e.g. pre-malignant, non-malignant, or dysplastic tissue, etc.) was collected for HCMI for this case. ***Note: If yes, proceed to Question 183.***
183	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
184	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
185	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
186	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.



Enrollment: Breast

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
187	Other method of cancer sample procurement	☐ Needle biopsy ☐ Lumpectomy ☐ Simple mastectomy ☐ Modified radical mastectomy ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 187a, otherwise, skip to Question 188.***
187a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
188	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
189	Tissue type	☐ Non-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 189a, otherwise, skip to Question 190.***
189a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
190	Anatomic site of OTHER tissue	☐ Left breast ☐ Right breast ☐ Bone ☐ Brain ☐ Liver ☐ Lung ☐ Lymph node ☐ Skin ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 190a, otherwise, skip to Question 191.***
190a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.
191	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
192	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Additional OTHER biospecimen Information (if applicable)				
193	Are you submitting an additional OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an additional OTHER tissue sample (pre-malignant, non-malignant, or dysplastic tissue, etc.) is being submitted for HCMI for this case. ***Note: If yes, proceed to Question 194, otherwise, skip to Question 204.***
194	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
195	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
196	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
197	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.



Enrollment: Breast

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
198	Other method of cancer sample procurement	☐ Needle biopsy ☐ Lumpectomy ☐ Simple mastectomy ☐ Modified radical mastectomy ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 198a, otherwise, skip to Question 199.***
198a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
199	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
200	Tissue type	☐ Non-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 200a, otherwise, skip to Question 201.***
200a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
201	Anatomic site of OTHER tissue	☐ Left breast ☐ Right breast ☐ Bone ☐ Brain ☐ Liver ☐ Lung ☐ Lymph node ☐ Skin ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 201a, otherwise, skip to Question 202.***
201a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.
202	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
203	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Other Tissue Model Information				
204	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
205	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
206	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
207	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
208	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.
Additional Other Tissue Model Information (if applicable)				
209	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***



Enrollment: Breast

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
210	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
211	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
212	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
213	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.



Enrollment: Colon/Rectum

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Form Notes: An Enrollment Form should be completed for each HCMI case upon qualification notice from Leidos. All information provided on this form should include activity from the Date of Initial Pathologic Diagnosis to the most recent Date of Last Contact with the patient.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	☐ Initial pathologic diagnosis ☐ Sample procurement ☐ First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.
Patient Information				
4	Gender	☐ Male ☐ Female ☐ Unspecified	2200604	Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
5	Height	_____	649	Provide the patient's height, in centimeters.
6	Weight	_____	651	Provide the patient's weight, in kilograms.
7	Body mass index (BMI)	_____	2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
8	Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown ☐ Not reported	2192199	Provide the patient's race using the defined categories. **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 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. **Black or African American:** A person having origins in any of the black racial groups of Africa. **Native Hawaiian or other Pacific Islander:** A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island. **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
9	Ethnicity	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Not reported	2192217	Provide the patient's ethnicity using the defined categories. **Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. **Not Hispanic or Latino:** A person not meeting the definition of Hispanic or Latino.



Enrollment: Colon/Rectum

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
10	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.
11	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. ***Note: If the patient's age is greater than 32,872 days (90 years), please enter 32,872.***
12	Year of birth	_____	2896954	Provide the year of the patient's birth. If the patient was born prior to 1928, insert the date 1928.
13	Family history of cancer	☐ Same ☐ Different ☐ None ☐ Unknown	5832923	Has a first-degree relative of the patient been diagnosed with a cancer of the same or a different type?
14	Smoking history	☐ Lifelong non-smoker (<100 cigarettes smoked in a lifetime) ☐ Current smoker (includes daily and non-daily smokers) ☐ Current reformed smoker (duration not specified) ☐ Current reformed smoker for >15 years ☐ Current reformed smoker for ≤15 years	2181650	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories.
15	Metastasis at diagnosis assessment status	☐ Metastatic ☐ Non-metastatic (confirmed) ☐ Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor. ***Note: If metastatic at diagnosis, proceed to Question 16, otherwise, skip to Question 17.***
16	Metastatic site(s) at diagnosis	☐ Brain ☐ Liver ☐ Lung ☐ Lymph Nodes ☐ Peritoneum ☐ Other (specify)	3029815	Indicate the site(s) of metastasis at the time of diagnosis of the primary tumor. ***Note: If the anatomic site of tumor tissue is not listed, proceed to Question 16a, otherwise, skip to Question 17.***
16a	Specify metastatic site(s)	_____	3128033	If the site of metastasis is not included on the provided list, specify the site of metastasis.
17	Did the patient have colorectal cancer risk factors?	☐ Yes ☐ No ☐ Unknown	5206897	Indicate whether additional colorectal cancer risk factors are documented in the patient's medical record. ***Note: If no colorectal cancer risk factors have been identified, skip to Question 19.***
18	Colorectal cancer risk factors	☐ A diet that is high in red meats and processed meats ☐ Diagnosis of familial adenomatous polyposis in patient or family member ☐ Obesity - weight > 20% ideal body weight ☐ Previous colorectal polyps ☐ Diagnosis of Lynch syndrome in patient ☐ Type II diabetes ☐ Other risk factors (specify)	5206898	Select all of the colorectal cancer risk factors documented in the patient's medical record. ***Note: If the colorectal cancer risk factor is not listed, proceed to Question 18a, otherwise, skip to Question 19.***
18a	Other colorectal cancer risk factor(s)	_____	5206899	If the patient's colorectal cancer risk factors were not included in the previous list, please specify.
19	Does the patient have a history of gastrointestinal disorder?	☐ Yes ☐ No ☐ Unknown	3521240	Indicate whether the patient has been diagnosed with gastrointestinal disorder(s). ***Note: If the patient was not diagnosed with gastrointestinal disorder, skip to Question 21.***



Enrollment: Colon/Rectum

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
20	Gastrointestinal disorder(s) diagnosed	☐ Adenomatous polyposis coli ☐ Hereditary non-polyposis colon cancer ☐ Peutz-Jeghers disease ☐ Ulcerative colitis ☐ Crohn disease ☐ Celiac disease	3211626	Select all the gastrointestinal disorder(s) with which the patient has been diagnosed.
21	History of synchronous colon/rectal tumors at time of tissue collection	☐ Yes ☐ No	2185953	Indicate whether synchronous colon or rectal tumors were present time of tissue collection.
22	History of prior colon polyps	☐ Yes ☐ No ☐ Unknown	3107197	Indicate if the patient had a previous history of colon polyps as noted in the history/physical or previous endoscopic report(s).
23	Were colon polyps present at time of tissue collection?	☐ Yes ☐ No ☐ Unknown	64184	Indicate if polyps were present in the colon surgically or pathologically at the time of tissue collection.
Biospecimen Information				
24	Tissue sample type(s) collected for HCMI for this case	☐ Normal tissue ☐ Primary tumor ☐ Metastatic ☐ Recurrent ☐ Other tissue	2006911	Please select all the tissue sample types submitted for HCMI with this case.
25	Number of NORMAL tissues biospecimens collected for HCMI for this case	_____	6584256	Please provide the number of normal tissue specimens obtained for HCMI for this case. ***Note: This number is expected to be 1.***
26	Number of PRIMARY cancer tissue biospecimens collected for HCMI model development for this case	_____	6584257	Please provide the number of primary tumor specimens obtained for HCMI for this case. ***Note: A single primary tumor biospecimen obtained that is portioned for both sequencing and model generation counts as 1 single primary tumor specimen. This number is expected to be 1.***
27	Number of METASTATIC/RECURRENT cancer tissue biospecimens collected for HCMI model development for this case	_____	6584258	Please provide the number of metastatic and/or recurrent cancer biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
28	Number of OTHER tissue biospecimens collected for HCMI model development for this case	_____	6584259	Please provide the number of pre-malignant, non-malignant, or dysplastic tissue biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
29	Total number of tissue biospecimens collected for HCMI for this case	_____	6584271	Please provide the total number of tissue biospecimens collected for HCMI for this case. ***Note: This number should be the sum of the normal, primary tumor, metastatic/ recurrent tumor, and other biospecimen counts above.***



Enrollment: Colon/Rectum

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Normal Control Information				
30	Normal tissue biospecimen ordinal	_____	6584264	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
31	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
32	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
33	Type of normal control	☐ Whole blood ☐ Buccal cells ☐ Buffy coat ☐ Lymphocytes ☐ Extracted DNA from blood ☐ Extracted DNA from saliva ☐ Extracted DNA from buccal cells ☐ Extracted DNA from normal tissue ☐ FFPE non-neoplastic tissue ☐ Non-neoplastic tissue	3081936	Indicate the type of normal control submitted for this case.
34	Anatomic site of normal tissue	☐ Ascending colon ☐ Cecum ☐ Descending colon ☐ Hepatic flexure ☐ Rectosigmoid junction ☐ Rectum ☐ Sigmoid colon ☐ Splenic flexure ☐ Transverse colon ☐ Other (specify) ☐ Not applicable	4132152	If non-neoplastic tissue was submitted as the normal control, select the anatomic site of the normal tissue. ***Note: If the anatomic site of normal tissue is not listed, proceed to Question 34a, otherwise, skip to Question 35.***
34a	Other anatomic site of normal tissue	_____	3288189	If non-neoplastic tissue, adjacent tissue, or normal tissue from another anatomic site was submitted as the normal control, provide the anatomic site of the normal tissue.
35	Distance from tumor to normal control tissue (if not blood)	☐ Adjacent (< or = 2cm) ☐ Distal (>2cm) ☐ Unknown ☐ Not applicable	3088708	Indicate the distance from the site of normal tumor collection to the primary tumor. ***Note: If normal tissue was not submitted, select 'Not applicable'.***
36	Normal tissue sample preservation method	☐ Cryopreserved ☐ OCT ☐ FFPE ☐ Snap frozen ☐ Frozen	5432521	Provide the method used to preserve the normal tissue sample collected for molecular characterization.
Primary Tumor Biospecimen Information				
37	ICD-10 code for primary tumor	☐ C18.0 ☐ C18.6 ☐ C77.9 ☐ C18.1 ☐ C18.7 ☐ C78.0 ☐ C18.2 ☐ C18.8 ☐ C78.6 ☐ C18.3 ☐ C18.9 ☐ C78.7 ☐ C18.4 ☐ C19 ☐ C79.3 ☐ C18.5 ☐ C20 ☐ Other (specify)	3226287	Provide the ICD-10 code for the primary tumor as used to generate the ID3 for this subject. ***Note: If the ICD-10 code is not listed, proceed to 37a, otherwise, skip to Question 38.***
37a	Other ICD-10 code for primary tumor	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.



Enrollment: Colon/Rectum

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
38	Tumor Morphology	☐ 8013/3 ☐ 8140/3 ☐ 8490/3 ☐ 8020/3 ☐ 8213/0 ☐ 8510/3 ☐ 8032/3 ☐ 8246/3 ☐ 8560/3 ☐ 8041/3 ☐ 8480/3 ☐ Other (specify) ☐ 8070/3	3226275	Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor. ***Note: If the ICD-O-3 histology code of the primary tumor is not listed, proceed to Question 38a, otherwise, skip to Question 39.***
38a	Specify other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.
39	Tissue or organ of origin	☐ Colon ☐ Rectum ☐ Other (specify)	3427536	Using the patient's pathology/laboratory report, select the primary site of the disease. ***Note: If the primary site of the disease is not listed, proceed to Question 39a, otherwise skip to Question 40.***
39a	Other tissue or organ of origin	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	3427536	If the primary site of the disease is not included on the previous list, provide the primary site of the disease.
40	Histological Type	☐ Colon cancer ☐ Colorectal cancer ☐ Rectal cancer ☐ Other (specify)	3081932	Select the surgical pathology text description of the histological tumor type. ***Note: If the histological tumor type is not listed, proceed to Question 40a, otherwise, skip to Question 41.***
40a	Other histological type	_____	3294805	If the traditional surgical pathology text description of the histological tumor type is not included on the previous list, please specify the histological type.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
41	Histological subtype	☐ Adenocarcinoma ☐ Adenosquamous carcinoma ☐ Large cell neuroendocrine carcinoma ☐ Medullary carcinoma ☐ Micropapillary carcinoma ☐ Mucinous adenocarcinoma ☐ Neuroendocrine carcinoma (poorly differentiated) ☐ Serrated adenocarcinoma ☐ Signet ring cell carcinoma ☐ Small cell neuroendocrine carcinoma ☐ Squamous cell carcinoma ☐ Undifferentiated carcinoma ☐ Carcinoma; type cannot be determined ☐ Other (specify)	3081934	Using the patient's pathology/laboratory report, select the histological subtype of the primary tumor. ***Note: If the histological subtype is not listed, proceed to Question 41a, otherwise, skip to Question 42.***
41a	Other histological subtype	_____	5946219	If the histological subtype for the primary tumor is not included in the provided list, specify the histological subtype.
42	Prior malignancy (of the same cancer type)	☐ Yes ☐ No ☐ Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
43	Prior malignancy (other cancer type)	☐ Yes ☐ No ☐ Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.
44	AJCC cancer staging edition	☐ 1st ☐ 4th ☐ 7th ☐ 2nd ☐ 5th ☐ 8th ☐ 3rd ☐ 6th	2722309	Select the AJCC staging handbook edition used to stage the patient's primary tumor.
45	AJCC clinical stage group	☐ Stage 0 ☐ Stage I ☐ Stage IIA ☐ Stage IIB ☐ Stage IIC ☐ Stage IIIA ☐ Stage IIIB ☐ Stage IIIC ☐ Stage IVA ☐ Stage IVB ☐ Stage IVC	3440332	Using the patient's pathology/laboratory report, select the clinical stage group of the primary tumor as defined by the American Joint Committee on Cancer (AJCC).
46	AJCC pathologic spread: Primary tumor (pT)	☐ T0 ☐ T2 ☐ T4a ☐ Tis ☐ T3 ☐ T4b ☐ T1 ☐ T4 ☐ TX	3045435	Using the patient's pathology/laboratory report, select the code for the pathologic T (primary tumor) as defined by the American Joint Committee on Cancer (AJCC).
47	AJCC pathologic spread: Lymph nodes (pN)	☐ N0 ☐ N1b ☐ N2a ☐ N1 ☐ N1c ☐ N2b ☐ N1a ☐ N2 ☐ NX	3203106	Using the patient's pathology/laboratory report, select the code for the pathologic N (nodal) as defined by the American Joint Committee on Cancer (AJCC).
48	AJCC pathologic spread: Distant metastases (pM)	☐ M0 ☐ M1a M1c ☐ M1 ☐ M1b	3045439	Using the patient's pathology/laboratory report, select the code for the pathologic M (metastasis) as defined by the American Joint Committee on Cancer (AJCC).
49	AJCC tumor stage (pathological)	☐ Stage 0 ☐ Stage I ☐ Stage IIA ☐ Stage IIB ☐ Stage IIC ☐ Stage IIIA ☐ Stage IIIB ☐ Stage IIIC ☐ Stage IVA ☐ Stage IVB ☐ Stage IVC	3065862	Using the patient's pathology/laboratory report, in conjunction with the patient's medical record, select the tumor stage as defined by the American Joint Committee on Cancer (AJCC).
50	Tumor grade	☐ G1-Well differentiated ☐ G2-Moderately differentiated ☐ G3-Poorly differentiated ☐ G4-Undifferentiated ☐ GB-Borderline histologic grade ☐ GX-Unknown	2785839	Using the patient's pathology/laboratory report, select the grade of the primary tumor.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
51	Venous invasion present?	☐ Yes ☐ No ☐ Unknown	64358	Indicate whether venous invasion was present in the tumor specimen. ***Note: If venous invasion is not present, skip to Question 53.***
52	Venous invasion type	☐ Extramural ☐ Intramural	6036344	Identify the location of vascular involvement for the tumor.
53	Lymphatic invasion present?	☐ Yes ☐ No ☐ Unknown	64171	Indicate if malignant cells are present in small or thin-walled vessels, suggesting lymphatic involvement.
54	Perineural invasion present?	☐ Yes ☐ No ☐ Unknown	64181	Indicate if perineural invasion or infiltration of tumor or cancer is present.
55	Preoperative CEA level	_____	2752	Provide the carcinoembryonic antigen (CEA) level (ng/ml) prior to resection of the tumor submitted to HCMI.
Primary Tumor Clinical Molecular Characterization				
56	Microsatellite instability identified?	☐ Yes ☐ No ☐ Unknown	3123142	Indicate whether microsatellite instability was present in more than 33% of loci tested. ***Note: If not performed, skip to Question 59.***
57	Number of loci tested	☐ 1 ☐ 8 ☐ 15 ☐ 2 ☐ 9 ☐ 16 ☐ 3 ☐ 10 ☐ 17 ☐ 4 ☐ 11 ☐ 18 ☐ 5 ☐ 12 ☐ 19 ☐ 6 ☐ 13 ☐ 20 ☐ 7 ☐ 14	3107127	Provide the number of loci tested to detect microsatellite instability.
58	Number of abnormal loci	☐ 1 ☐ 8 ☐ 15 ☐ 2 ☐ 9 ☐ 16 ☐ 3 ☐ 10 ☐ 17 ☐ 4 ☐ 11 ☐ 18 ☐ 5 ☐ 12 ☐ 19 ☐ 6 ☐ 13 ☐ 20 ☐ 7 ☐ 14	3107129	Provide the number of loci found to be abnormal during testing to detect microsatellite instability.
59	Mismatch repair status	☐ Evidence of MMR mutation by sequencing ☐ Evidence of MMR protein loss by IHC ☐ MMR loss evidence hypermutation phenotype (>10 mutations/Mb) ☐ No evidence of MMR alteration	6002208	Indicate the mismatch repair (MMR) status and the mechanism by which it was determined.
60	Was MLH1 IHC performed?	☐ Yes ☐ No ☐ Unknown	6062411	Indicate whether MLH1 expression was assessed by immunohistochemistry (IHC). ***Note: If not performed, skip to Question 62.***
61	MLH1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063668	Indicate the status of MLH1 protein expression as determined by immunohistochemistry (IHC).
62	MLH1 promoter methylation status	☐ MLH1 promoter hypermethylation present ☐ MLH1 promoter hypermethylation absent ☐ MLH1 promoter hypermethylation not assessed ☐ Cannot be determined	6033150	Indicate the methylation status of the MLH1 promoter.
63	Was MSH2 IHC performed	☐ Yes ☐ No ☐ Unknown	6062412	Indicate whether MSH2 expression was assessed by immunohistochemistry (IHC). ***Note: If not performed, skip to Question 65.***



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
64	MSH2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063669	Indicate the status of MSH2 protein expression as determined by immunohistochemistry (IHC).
65	Was PMS2 IHC performed	☐ Yes ☐ No ☐ Unknown	6062413	Indicate whether PMS2 expression was assessed by immunohistochemistry (IHC). ***Note: If not performed, skip to Question 67.***
66	PMS2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063670	Indicate the status of PMS2 protein expression as determined by immunohistochemistry (IHC).
67	Was MSH6 IHC performed?	☐ Yes ☐ No ☐ Unknown	6062414	Indicate whether MSH6 expression was assessed by immunohistochemistry (IHC). ***Note: If not performed, skip to Question 69.***
68	MSH6 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063671	Indicate the status of MSH6 protein expression as determined by immunohistochemistry (IHC).
69	Was KRAS mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6060079	Indicate whether KRAS mutation analysis was performed. ***Note: If not performed, skip to Question 72.***
70	Was a mutation in KRAS identified	☐ Yes ☐ No	6060081	Indicate whether a mutation in KRAS was identified through mutation analysis. ***Note: If mutation was not identified, skip to Question 72.***
71	If KRAS mutation identified, which one?	☐ G12A ☐ G12V ☐ G13V ☐ G12C ☐ G13D ☐ Q61L ☐ G12D ☐ G13R ☐ Q61H ☐ G12R ☐ G13C ☐ A146T ☐ G12S ☐ G13A ☐ Other (specify)	6060083	Indicate the specific KRAS mutation identified. ***Note: If the KRAS mutation is not listed, proceed to Question 71a, otherwise, skip to Question 72.***
71a	Other KRAS mutation(s)	_____	6101691	If the KRAS mutation identified is not provided in the previous list, specify the KRAS mutation.
72	Was BRAF mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6061813	Indicate whether BRAF mutation analysis was performed. ***Note: If not performed, skip to Question 75.***
73	Was a mutation in BRAF identified?	☐ Yes ☐ No	6061809	Indicate whether a mutation in BRAF was identified through mutation analysis. ***Note: If mutation was not identified, skip to Question 75.***
74	If BRAF mutation identified, which one?	☐ V600E ☐ V600R ☐ V600D ☐ K601E ☐ V600K ☐ Other (specify)	6061810	Indicate the specific BRAF mutation identified. ***Note: If the BRAF mutation is not listed, proceed to Question 74a, otherwise, skip to Question 75.***
74a	Other BRAF mutation	_____	6101687	If the BRAF mutation is not included in the list provided, specify the BRAF mutation identified.
75	Was BRAF IHC performed?	☐ Yes ☐ No ☐ Unknown	6161811	Indicate whether BRAF expression was assessed by immunohistochemistry (IHC). ***Note: If not performed, skip to Question 77.***
76	BRAF expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6061812	Indicate the status of BRAF protein expression as determined by immunohistochemistry (IHC).
77	Was PIK3CA mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063445	Indicate whether PIK3CA mutation analysis was performed. ***Note: If not performed, skip to Question 80.***
78	Was a mutation in PIK3CA identified?	☐ Yes ☐ No	6063524	Indicate whether a mutation in PIK3CA was identified through mutation analysis. ***Note: If mutation was not identified, skip to Question 80.***



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
79	If PIK3CA mutation identified, in what exon?	☐ 9 ☐ 20 ☐ Other (specify)	6063735	Indicate the specific exon of the PIK3CA gene in which the mutation was identified. ***Note: If the PIK3CA mutation is not listed, proceed to Question 79a, otherwise, skip to Question 80.***
79a	Other PIK3CA mutation	_____	6101688	If the specific exon of the PIK3CA gene mutation abnormality identified was not included in the previous list, please specify the exon.
80	Was PTEN IHC performed?	☐ Yes ☐ No ☐ Unknown	6062415	Indicate whether PTEN expression was assessed by immunohistochemistry (IHC). ***Note: If not performed, skip to Question 82.***
81	PTEN expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063672	Indicate the status of PTEN protein expression as determined by immunohistochemistry (IHC).
82	Was PTEN mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063446	Indicate whether PTEN mutation analysis was performed. ***Note: If not performed, skip to Question 85.***
83	Was a mutation in PTEN identified	☐ Yes ☐ No	6063529	Indicate whether a mutation in PTEN was identified through mutation analysis.
84	If PTEN mutation identified, which one?	☐ Exon 1-9 mutation present ☐ Cannot be determined ☐ Other (specify)	6063736	Indicate whether a mutation in exon 1-9 of PTEN was identified. ***Note: If the PTEN mutation is not listed, proceed to Question 84a, otherwise, skip to Question 85.***
84a	Other PTEN mutation	_____	6101689	If the PTEN gene mutation identified is not in exons 1-9, please specify the exon.
Primary Tumor Sample Information				
85	Are you submitting a primary tumor tissue sample for this case?	☐ Yes ☐ No		***If yes, proceed to question 86.*** ***If no and submitting a metastatic/recurrent tumor sample, proceed to Question 112.***
86	Primary tumor biospecimen ordinal	_____	6584265	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number should be "1".***
87	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
88	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
89	Sample represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this primary tumor specimen represent the PRIMARY DIAGNOSIS for this Case ID3? ***Note: If no, continue to Question 90, otherwise, skip to Question 91.***
90	Specify the ICD-10 code	_____	3226287	Provide the ICD-10 code for the primary tumor used to generate the model submitted to HCMI.
91	Tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the tumor tissue sample collected for molecular characterization.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
92	Anatomic Site of tumor from which Model was Derived	☐ Ascending colon ☐ Ascending colon hepatic flexure ☐ Cecum ☐ Descending colon ☐ Ileocecal valve ☐ Rectosigmoid junction ☐ Rectum ☐ Sigmoid colon ☐ Splenic flexure ☐ Transverse colon ☐ Brain ☐ Liver ☐ Lung ☐ Lymph node ☐ Peritoneum ☐ Other (specify)	6033148	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI. ***Note: If the tissue or organ of origin is not listed, proceed to Question 92a. Otherwise, skip to Question 93.***
92a	Other anatomic site from which the tumor was obtained	_____	5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.
93	Method of cancer sample procurement	☐ Abdomino-perineal resection ☐ Anterior resection of rectum ☐ Endo-rectal tumor resection ☐ Left hemicolectomy ☐ Pan-proto colectomy ☐ Right hemicolectomy ☐ Sigmoid colectomy ☐ Total colectomy ☐ Transverse colectomy ☐ Other (specify)	3103514	Provide the procedure performed to obtain the primary tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 93a, otherwise, skip to Question 94.***
93a	Specify the other method of tumor sample procurement	_____	2006730	Specify the procedure performed to obtain the primary tumor tissue, if not included in the previous list.
94	Number of days from index date to date of tumor sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the tumor tissue submitted for HCMI.
95	Tumor tissue type	☐ Primary ☐ Additional Primary ☐ NOS	3288124	Provide the primary tumor tissue type for this sample.
Primary Tumor Model Information				
96	Primary model biospecimen ordinal	_____	6594596	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number is expected to be "1".***
97	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
98	BPC submitter ID (if available)		6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
99	Model represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this MODEL represent the PRIMARY DIAGNOSIS for this Case ID3?
100	Model's primary tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the PRIMARY TUMOR TISSUE from which this model is derived.
101	Model's primary tumor biospecimen ordinal	_____	6584265	Enter the biospecimen ordinal of the PRIMARY TUMOR TISSUE from which this model is derived.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Treatment Information				
102	History of neoadjuvant treatment	☐ No ☐ Yes; radiation prior to resection ☐ Yes; pharmaceutical treatment prior to resection ☐ Yes; both radiation and pharmaceutical treatment prior to resection ☐ Unknown	3382737	Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment. ***Note: Radiation therapy is addressed in Questions 110-111. Pharmaceutical therapy is addressed in Questions 103-109.***
103	Neoadjuvant chemotherapy type	☐ Cytotoxic chemotherapy ☐ Immunotherapy (cellular and immune checkpoint) ☐ Targeted therapy (small molecule inhibitors and targeted antibodies) ☐ Not applicable	5832928	Select all neoadjuvant chemotherapy types that were administered to the patient. ***Note: Cytotoxic chemotherapy is addressed in Questions 104-105. Immunotherapy is addressed in Questions 106-107. Targeted therapy is addressed in Questions 108-109.***
104	Neoadjuvant chemotherapeutic regimen	☐ 5-fluorouracil ☐ 5-FU and Leucovorin ☐ Capecitabine ☐ FOLFIRI ☐ FOLFOX ☐ Irinotecan ☐ Leucovorin ☐ Oxaliplatin ☐ Trifluridine ☐ Trifluridine and tipiracil ☐ Other (specify) ☐ Chemotherapy not given	2853313	Select all chemotherapeutics used for neoadjuvant therapy. ***Note: If neoadjuvant chemotherapy was not given, skip to Question 106. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 104a, otherwise, skip to Question 105.***
104a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapies administered.
105	Days to neoadjuvant chemotherapy treatment from index date	_____	5102411	Provide the number of days from index date to the date of treatment with neoadjuvant chemotherapy.
106	Immunotherapy name, specify	_____	2953828	Provide the name of the immunotherapy administered to the patient. ***Note: If immunotherapy was not administered, skip to Question 108.***
107	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
108	Targeted Therapy	☐ Bevacizumab ☐ Cetuximab ☐ Panitumumab ☐ PD-1 inhibitor ☐ Ramucirmab ☐ Regorafenib ☐ Ziv-aflibercept ☐ Other (specify)	6033149	Select the targeted molecular therapy administered to the patient. ***Note: If targeted therapy was not given, proceed to Question 110. If the targeted therapy is not listed, proceed to Question 108a, otherwise, skip to Question 109.***
108a	Specify targeted therapy	_____	4308476	Provide the name of the targeted therapy administered to the patient.
109	Days to targeted therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with targeted therapy.
110	Radiation therapy administered type	☐ 2D conventional ☐ 3D conformal ☐ Brachytherapy HDR ☐ Brachytherapy LDR ☐ IMRT ☐ Proton Beam ☐ Stereotactic Body RT ☐ Stereotactic Radiosurgery ☐ WBRT ☐ Other (specify) ☐ Unspecified ☐ Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. ***Note: If radiation therapy was not administered, proceed to Question 112. If the radiation therapy is not listed, proceed to Question 110a, otherwise, skip to Question 111.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
110a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
111	Days to radiation treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with radiation therapy.
Metastatic/Recurrent Tumor Biospecimen Information				
112	Are you submitting a metastatic/recurrent tumor tissue sample?	☐ Yes ☐ No		Indicate whether a metastatic/recurrent tumor biospecimen was collected for this ID3 case. ***Note: If yes, proceed to Question 113. If submitting an OTHER tissue sample, proceed to Question 219.***
113	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1", the second should be number "2", etc.***
114	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
115	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
116	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
117	Number of days from index date to date of diagnosis of metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic/recurrent disease.
118	Method of metastatic/ recurrent cancer sample procurement	☐ Abdomino-perineal resection ☐ Anterior resection of rectum ☐ Endo-rectal tumor resection ☐ Left hemicolectomy ☐ Pan-proto colectomy ☐ Right hemicolectomy ☐ Sigmoid colectomy ☐ Total colectomy ☐ Transverse colectomy ☐ Other (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 118a, otherwise, skip to Question 119.***
118a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
119	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
120	Metastatic/ recurrent site	☐ Cecum ☐ Ileocecal valve ☐ Sigmoid colon ☐ Splenic flexure ☐ Ascending colon ☐ Ascending colon hepatic flexure ☐ Descending colon ☐ Transverse colon ☐ Rectum ☐ Rectosigmoid junction ☐ Liver ☐ Brain ☐ Lung ☐ Peritoneum ☐ Lymph node ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 120a, otherwise, skip to Question 121.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
120a	Other metastatic/ recurrent site	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
121	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
122	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
123	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
124	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
125	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
126	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
127	Is the patient still receiving treatment?	_____	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
128	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
129	Venous invasion present?	☐ Yes ☐ No ☐ Unknown	64358	Indicate whether venous invasion was present in the tumor specimen. ***Note: If venous invasion is not present, skip to Question 131.***
130	Venous invasion type	☐ Extramural ☐ Intramural	6036344	Identify the location of vascular involvement for the tumor.
131	Lymphatic invasion present?	☐ Yes ☐ No ☐ Unknown	64171	Indicate if malignant cells are present in small or thin-walled vessels, suggesting lymphatic involvement.
132	Perineural invasion present?	☐ Yes ☐ No ☐ Unknown	64181	Indicate if perineural invasion or infiltration of tumor or cancer is present.
133	Preoperative CEA level	_____	2752	Provide the carcinoembryonic antigen (CEA) level (ng/ml) prior to resection of the tumor submitted to HCMI.
Metastatic/Recurrent Tumor Sample: Clinical Molecular Analyses				
134	Microsatellite instability identified?	☐ Yes ☐ No ☐ Unknown	3123142	Indicate whether microsatellite instability was present in more than 33% of loci tested. ***Note: If not performed, skip to Question 137.***
135	Number of loci tested	☐ 1 ☐ 8 ☐ 15 ☐ 2 ☐ 9 ☐ 16 ☐ 3 ☐ 10 ☐ 17 ☐ 4 ☐ 11 ☐ 18 ☐ 5 ☐ 12 ☐ 19 ☐ 6 ☐ 13 ☐ 20 ☐ 7 ☐ 14	3107127	Provide the number of loci tested to detect microsatellite instability.
136	Number of abnormal loci	☐ 1 ☐ 8 ☐ 15 ☐ 2 ☐ 9 ☐ 16 ☐ 3 ☐ 10 ☐ 17 ☐ 4 ☐ 11 ☐ 18 ☐ 5 ☐ 12 ☐ 19 ☐ 6 ☐ 13 ☐ 20 ☐ 7 ☐ 14	3107129	Provide the number of loci found to be abnormal during testing to detect microsatellite instability.
137	Mismatch repair status	☐ Evidence of MMR mutation by sequencing ☐ Evidence of MMR protein loss by IHC ☐ MMR loss evidence hypermutation phenotype (>10 mutations/Mb) ☐ No evidence of MMR alteration	6002208	Indicate the mismatch repair (MMR) status and the mechanism by which it was determined.
138	Was MLH1 IHC performed?	☐ Yes ☐ No ☐ Unknown	6062411	Indicate whether MLH1 expression was assessed by immunohistochemistry (IHC). ***Note: If not performed, skip to Question 140.***
139	MLH1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063668	Indicate the status of MLH1 protein expression as determined by immunohistochemistry (IHC).



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
140	MLH1 promoter methylation status	☐ MLH1 promoter hypermethylation present ☐ MLH1 promoter hypermethylation absent ☐ MLH1 promoter hypermethylation not assessed ☐ Cannot be determined	6033150	Indicate the methylation status of the MLH1 promoter.
141	Was MSH2 IHC performed	☐ Yes ☐ No ☐ Unknown	6062412	Indicate whether MSH2 expression was assessed by immunohistochemistry (IHC). ***Note: If not performed, skip to Question 143.***
142	MSH2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063669	Indicate the status of MSH2 protein expression as determined by immunohistochemistry (IHC).
143	Was PMS2 IHC performed	☐ Yes ☐ No ☐ Unknown	6062413	Indicate whether PMS2 expression was assessed by immunohistochemistry (IHC). ***Note: If not performed, skip to Question 145.***
144	PMS2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063670	Indicate the status of PMS2 protein expression as determined by immunohistochemistry (IHC).
145	Was MSH6 IHC performed?	☐ Yes ☐ No ☐ Unknown	6062414	Indicate whether MSH6 expression was assessed by immunohistochemistry (IHC). ***Note: If not performed, skip to Question 147.***
146	MSH6 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063671	Indicate the status of MSH6 protein expression as determined by immunohistochemistry (IHC).
147	Was KRAS mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6060079	Indicate whether KRAS mutation analysis was performed. ***Note: If not performed, skip to Question 150.***
148	Was a mutation in KRAS identified	☐ Yes ☐ No	6060081	Indicate whether a mutation in KRAS was identified through mutation analysis. ***Note: If mutation was not identified, skip to Question 150.***
149	If KRAS mutation identified, which one?	☐ G12A ☐ G12C ☐ G12D ☐ G12R ☐ G12S ☐ G12V ☐ G13D ☐ G13R ☐ G13C ☐ G13A ☐ G13V ☐ Q61L ☐ Q61H ☐ A146T ☐ Other (specify)	6060083	Indicate the specific KRAS mutation identified. ***Note: If the KRAS mutation is not listed, proceed to Question 149a, otherwise, skip to Question 150.***
149a	Other KRAS mutation(s)	_____	6101691	If the KRAS mutation identified is not provided in the previous list, specify the KRAS mutation.
150	Was BRAF mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6061813	Indicate whether BRAF mutation analysis was performed. ***Note: If not performed, skip to Question 153.***
151	Was a mutation in BRAF identified?	☐ Yes ☐ No	6061809	Indicate whether a mutation in BRAF was identified through mutation analysis. ***Note: If mutation was not identified, skip to Question 153.***
152	If BRAF mutation identified, which one?	☐ V600E ☐ V600D ☐ V600K ☐ V600R ☐ K601E ☐ Other (specify)	6061810	Indicate the specific BRAF mutation identified. ***Note: If the BRAF mutation is not listed, proceed to Question 152a, otherwise, skip to Question 153.***
152a	Other BRAF mutation	_____	6101687	If the BRAF mutation is not included in the list provided, specify the BRAF mutation identified.
153	Was BRAF IHC performed?	☐ Yes ☐ No ☐ Unknown	6161811	Indicate whether BRAF expression was assessed by immunohistochemistry (IHC). ***Note: If not performed, skip to Question 155.***



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
154	BRAF expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6061812	Indicate the status of BRAF protein expression as determined by immunohistochemistry (IHC).
155	Was PIK3CA mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063445	Indicate whether PIK3CA mutation analysis was performed. ***Note: If not performed, skip to Question 158.***
156	Was a mutation in PIK3CA identified?	☐ Yes ☐ No	6063524	Indicate whether a mutation in PIK3CA was identified through mutation analysis. ***Note: If mutation was not identified, skip to Question 158.***
157	If PIK3CA mutation identified, in what exon?	☐ 9 ☐ 20 ☐ Other (specify)	6063735	Indicate the specific exon of the PIK3CA gene in which the mutation was identified. ***Note: If the PIK3CA mutation is not listed, proceed to Question 157a, otherwise, skip to Question 158.***
157a	Other PIK3CA mutation	_____	6101688	If the specific exon of the PIK3CA gene mutation abnormality identified was not included in the previous list, please specify the exon.
158	Was PTEN IHC performed?	☐ Yes ☐ No ☐ Unknown	6062415	Indicate whether PTEN expression was assessed by immunohistochemistry (IHC). ***Note: If not performed, skip to Question 160.***
159	PTEN expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063672	Indicate the status of PTEN protein expression as determined by immunohistochemistry (IHC).
160	Was PTEN mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063446	Indicate whether PTEN mutation analysis was performed. ***Note: If not performed, skip to Question 163.***
161	Was a mutation in PTEN identified	☐ Yes ☐ No	6063529	Indicate whether a mutation in PTEN was identified through mutation analysis.
162	If PTEN mutation identified, which one?	☐ Exon 1-9 mutation present ☐ Cannot be determined ☐ Other (specify)	6063736	Indicate whether a mutation in exon 1-9 of PTEN was identified.
162a	Other PTEN mutation	_____	6101689	If the PTEN gene mutation identified is not in exons 1-9, please specify the exon.
Additional Metastatic/Recurrent Tumor Biospecimen Information (if applicable)				
163	Are you submitting an additional metastatic/ recurrent tumor tissue sample?	☐ Yes ☐ No		A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen. ***Note: If yes, proceed to Question 164, otherwise, skip to Question 209.***
164	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. The first biospecimen should be number "1," the second should be number "2," etc.
165	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
166	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
167	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
168	Number of days from index date to date of diagnosis of additional metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of additional metastatic/recurrent disease.
169	Method of metastatic/ recurrent cancer sample procurement	☐ Abdomino-perineal resection ☐ Anterior resection of rectum ☐ Endo-rectal tumor resection ☐ Left hemicolectomy ☐ Pan-proto colectomy ☐ Right hemicolectomy ☐ Sigmoid colectomy ☐ Total colectomy ☐ Transverse colectomy ☐ Other (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 169a, otherwise, skip to Question 170.***
169a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
170	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
171	Metastatic/ recurrent site	☐ Liver ☐ Lung ☐ Brain ☐ Peritoneum ☐ Lymph nodes ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 171a, otherwise, skip to Question 172.***
171a	Other metastatic/ recurrent site	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.



Enrollment: Colon/Rectum

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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		☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva		
172	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
173	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
174	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
175	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
176	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
177	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
178	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
178	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
Additional Metastatic/Recurrent Tumor Sample: Clinical Molecular Analyses				
179	Microsatellite instability identified?	☐ Yes ☐ No ☐ Unknown	3123142	Indicate whether microsatellite instability was present in more than 33% of loci tested. ***Note: If not performed, skip to Question 182.***
180	Number of loci tested	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15 ☐ 16 ☐ 17 ☐ 18 ☐ 19 ☐ 20	3107127	Provide the number of loci tested to detect microsatellite instability.
181	Number of abnormal loci	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15 ☐ 16 ☐ 17 ☐ 18 ☐ 19 ☐ 20	3107129	Provide the number of loci found to be abnormal during testing to detect microsatellite instability.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
182	Mismatch repair status	☐ Evidence of MMR mutation by sequencing ☐ Evidence of MMR protein loss by IHC ☐ MMR loss evidence hypermutation phenotype (>10 mutations/Mb) ☐ No evidence of MMR alteration	6002208	Indicate the mismatch repair (MMR) status and the mechanism by which it was determined.
183	Was MLH1 IHC performed?	☐ Yes ☐ No ☐ Unknown	6062411	Indicate whether MLH1 expression was assessed by immunohistochemistry (IHC). ***Note: If not performed, skip to Question 185.***
184	MLH1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063668	Indicate the status of MLH1 protein expression as determined by immunohistochemistry (IHC).
185	MLH1 promoter methylation status	☐ MLH1 promoter hypermethylation present ☐ MLH1 promoter hypermethylation absent ☐ MLH1 promoter hypermethylation not assessed ☐ Cannot be determined	6033150	Indicate the methylation status of the MLH1 promoter.
186	Was MSH2 IHC performed	☐ Yes ☐ No ☐ Unknown	6062412	Indicate whether MSH2 expression was assessed by immunohistochemistry (IHC). ***Note: If not performed, skip to Question 188.***
187	MSH2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063669	Indicate the status of MSH2 protein expression as determined by immunohistochemistry (IHC).
188	Was PMS2 IHC performed	☐ Yes ☐ No ☐ Unknown	6062413	Indicate whether PMS2 expression was assessed by immunohistochemistry (IHC). ***Note: If not performed, skip to Question 190.***
189	PMS2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063670	Indicate the status of PMS2 protein expression as determined by immunohistochemistry (IHC).
190	Was MSH6 IHC performed?	☐ Yes ☐ No ☐ Unknown	6062414	Indicate whether MSH6 expression was assessed by immunohistochemistry (IHC). ***Note: If not performed, skip to Question 192.***
191	MSH6 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063671	Indicate the status of MSH6 protein expression as determined by immunohistochemistry (IHC).
192	Was KRAS mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6060079	Indicate whether KRAS mutation analysis was performed. ***Note: If not performed, skip to Question 195.***
193	Was a mutation in KRAS identified	☐ Yes ☐ No	6060081	Indicate whether a mutation in KRAS was identified through mutation analysis. ***Note: If mutation was not identified, skip to Question 195.***
194	If KRAS mutation identified, which one?	☐ G12A ☐ G12C ☐ G12D ☐ G12R ☐ G12S ☐ G12V ☐ G13D ☐ G13R ☐ G13C ☐ G13A ☐ G13V ☐ Q61L ☐ Q61H ☐ A146T ☐ Other (specify)	6060083	Indicate the specific KRAS mutation identified. ***Note: If the KRAS mutation is not listed, proceed to Question 194a, otherwise, skip to Question 195.***
194a	Other KRAS mutation(s)	_____	6101691	If the KRAS mutation identified is not provided in the previous list, specify the KRAS mutation.
195	Was BRAF mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6061813	Indicate whether BRAF mutation analysis was performed. ***Note: If not performed, skip to Question 198.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
196	Was a mutation in BRAF identified?	☐ Yes ☐ No	6061809	Indicate whether a mutation in BRAF was identified through mutation analysis. ***Note: If mutation was not identified, skip to Question 198.***
197	If BRAF mutation identified, which one?	☐ V600E ☐ V600R ☐ V600D ☐ K601E ☐ V600K ☐ Other (specify)	6061810	Indicate the specific BRAF mutation identified. ***Note: If the BRAF mutation is not listed, proceed to Question 197a, otherwise, skip to Question 198.***
197a	Other BRAF mutation	_____	6101687	If the BRAF mutation is not included in the list provided, specify the BRAF mutation identified.
198	Was BRAF IHC performed?	☐ Yes ☐ No ☐ Unknown	6161811	Indicate whether BRAF expression was assessed by immunohistochemistry (IHC). ***Note: If not performed, skip to Question 200.***
199	BRAF expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6061812	Indicate the status of BRAF protein expression as determined by immunohistochemistry (IHC).
200	Was PIK3CA mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063445	Indicate whether PIK3CA mutation analysis was performed. ***Note: If not performed, skip to Question 203.***
201	Was a mutation in PIK3CA identified?	☐ Yes ☐ No	6063524	Indicate whether a mutation in PIK3CA was identified through mutation analysis. ***Note: If mutation was not identified, skip to Question 203.***
202	If PIK3CA mutation identified, in what exon?	☐ 9 ☐ 20 ☐ Other (specify)	6063735	Indicate the specific exon of the PIK3CA gene in which the mutation was identified. ***Note: If the PIK3CA mutation is not listed, proceed to Question 202a, otherwise, skip to Question 203.***
202a	Other PIK3CA mutation	_____	6101688	If the specific exon of the PIK3CA gene mutation abnormality identified was not included in the previous list, please specify the exon.
203	Was PTEN IHC performed?	☐ Yes ☐ No ☐ Unknown	6062415	Indicate whether PTEN expression was assessed by immunohistochemistry (IHC). ***Note: If not performed, skip to Question 205.***
204	PTEN expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063672	Indicate the status of PTEN protein expression as determined by immunohistochemistry (IHC).
205	Was PTEN mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063446	Indicate whether PTEN mutation analysis was performed. ***Note: If not performed, skip to Question 209.***
206	Was a mutation in PTEN identified	☐ Yes ☐ No	6063529	Indicate whether a mutation in PTEN was identified through mutation analysis.
207	If PTEN mutation identified, which one?	☐ Exon 1-9 mutation present ☐ Cannot be determined ☐ Other (specify)	6063736	Indicate whether a mutation in exon 1-9 of PTEN was identified. ***Note: If the PTEN mutation is not listed, proceed to Question 207a, otherwise, skip to Question 208.***
207a	Other PTEN mutation	_____	6101689	If the PTEN gene mutation identified is not in exons 1-9, please specify the exon.
Metastatic/Recurrent Tumor Model Information				
208	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
209	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
210	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
211	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
212	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Additional Metastatic/Recurrent Biospecimen Tumor Model Information (if applicable)				
213	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
214	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
215	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
216	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
217	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Other Biospecimen Information				
218	Are you submitting an OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an OTHER tissue sample (e.g. pre-malignant, non-malignant, or dysplastic tissue, etc.) was collected for HCMI for this case. ***Note: If yes, proceed to Question 219.***
219	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
220	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
221	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
222	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
223	Other method of cancer sample procurement	☐ Abdomino-perineal resection ☐ Anterior resection of rectum ☐ Endo-rectal tumor resection ☐ Left hemicolectomy ☐ Pan-proto colectomy ☐ Right hemicolectomy ☐ Sigmoid colectomy ☐ Total colectomy ☐ Transverse colectomy ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 223a, otherwise, skip to Question 224.***
223a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
224	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
225	Tissue type	☐ Non-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 225a, otherwise, skip to Question 226.***
225a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
226	Anatomic site of OTHER tissue	☐ Ascending colon ☐ Ascending colon hepatic flexure ☐ Cecum ☐ Descending colon ☐ Ileocecal valve ☐ Rectosigmoid junction ☐ Rectum ☐ Sigmoid colon ☐ Splenic flexure ☐ Transverse colon ☐ Brain ☐ Liver ☐ Lung ☐ Lymph node ☐ Peritoneum ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 226a, otherwise, skip to Question 227.***
226a	Specify anatomic site of OTHER tissue	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus	6584916	Specify the site of OTHER tissue, if not in the previous list.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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		☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva		
227	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
228	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Additional OTHER biospecimen Information (if applicable)				
229	Are you submitting an additional OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an additional OTHER tissue sample (pre-malignant, non-malignant, or dysplastic tissue, etc.) is being submitted for HCMI for this case. ***Note: If yes, proceed to Question 230. If no, proceed to Question 240.***
230	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. The first biospecimen should be number "1," the second should be number "2," etc.
231	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
232	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
233	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
234	Other method of cancer sample procurement	☐ Abdomino-perineal resection ☐ Anterior resection of rectum ☐ Endo-rectal tumor resection ☐ Left hemicolectomy ☐ Pan-proto colectomy ☐ Right hemicolectomy ☐ Sigmoid colectomy ☐ Total colectomy ☐ Transverse colectomy ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 234a, otherwise, skip to Question 235.***
234a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
235	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
236	Tissue type	☐ Non-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 236a, otherwise, skip to Question 237.***



Enrollment: Colon/Rectum

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
236a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
237	Anatomic site of OTHER tissue	☐ Ascending colon ☐ Ascending colon hepatic flexure ☐ Cecum ☐ Descending colon ☐ Ileocecal valve ☐ Rectosigmoid junction ☐ Rectum ☐ Sigmoid colon ☐ Splenic flexure ☐ Transverse colon ☐ Brain ☐ Liver ☐ Lung ☐ Lymph node ☐ Peritoneum ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 237a, otherwise, skip to Question 238.***
237a	Specify anatomic site of OTHER tissue	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	6584916	Specify the site of OTHER tissue, if not in the previous list.
238	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.



Enrollment: Colon/Rectum

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Question Text
239	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Other Tissue Model Information				
240	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
241	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
242	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
243	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
244	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.
Additional Other Tissue Model Information (if applicable)				
245	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
246	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
247	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
248	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
249	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.



Enrollment: Endometrium

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Form Notes: An Enrollment Form should be completed for each HCMI case upon qualification notice from Leidos. All information provided on this form should include activity from the Date of Initial Pathologic Diagnosis to the most recent Date of Last Contact with the patient. This form should be used for Endometrial Cancers and Uterine Sarcomas.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	☐ Initial pathologic diagnosis ☐ Sample procurement ☐ First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.
Patient Information				
4	Gender	☐ Male ☐ Female ☐ Unspecified	2200604	Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
5	Height	_____	649	Provide the patient's height, in centimeters.
6	Weight	_____	651	Provide the patient's weight, in kilograms.
7	Body mass index (BMI)	_____	2006410	Provide the patient's body mass index (BMI).
8	Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown ☐ Not reported	2192199	Provide the patient's race using the defined categories. **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 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. **Black or African American:** A person having origins in any of the black racial groups of Africa. **Native Hawaiian or other Pacific Islander:** A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island. **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
9	Ethnicity	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Not reported	2192217	Provide the patient's ethnicity using the defined categories. **Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. **Not Hispanic or Latino:** A person not meeting the definition of Hispanic or Latino.



Enrollment: Endometrium

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
10	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.
11	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. ***Note: If the patient's age is greater than 32,872 days (90 years), please enter 32,872.***
12	Year of birth	_____	2896954	Provide the year of the patient's birth. If the patient was born prior to 1928, insert the date 1928.
13	Family history of cancer	☐ Same ☐ Different ☐ None ☐ Unknown	5832923	Has a first-degree relative of the patient been diagnosed with a cancer of the same or a different type?
14	Smoking history	☐ Lifelong non-smoker (<100 cigarettes smoked in a lifetime) ☐ Current smoker (includes daily and non-daily smokers) ☐ Current reformed smoker (duration not specified) ☐ Current reformed smoker for >15 years ☐ Current reformed smoker for ≤15 years	2181650	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories.
15	Metastasis at diagnosis assessment status	☐ Metastatic ☐ Non-metastatic (confirmed) ☐ Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor. ***Note: If metastatic at diagnosis, proceed to Question 16, otherwise, skip to Question 17.***
16	Metastatic site(s) at diagnosis	☐ Extra-abdominal lymph node(s) ☐ Pelvic lymph node(s) ☐ Para-aortic lymph node(s) ☐ Peritoneum ☐ Lung ☐ Liver ☐ Adrenal gland ☐ Brain ☐ Bone ☐ Soft tissue ☐ Right ovary ☐ Left ovary ☐ Right fallopian tube ☐ Left fallopian tube ☐ Right tubo-ovarian ☐ Left tubo-ovarian ☐ Omentum ☐ Other (specify)	3029815	Indicate the site(s) of metastasis at the time of diagnosis of the primary tumor. ***Note: If the anatomic site of tumor tissue is not listed, proceed to Question 16a, otherwise, skip to Question 17.***
16a	Specify metastatic site(s)	_____	3128033	If the site of metastasis is not included on the provided list, specify the site of metastasis.
17	Clinical history (select all that apply)	☐ Lynch syndrome ☐ Breast cancer ☐ Other cancer (specify) ☐ Polycystic ovarian syndrome (PCOS) ☐ Endometriosis ☐ Metabolic syndrome ☐ Diabetes ☐ Other (specify)	6690684	Select all relevant prior diseases/disorders in the patient's clinical history. ***Note: If 'Other cancer' is selected, proceed to Question 17a, otherwise, skip to Question 18. If the clinical history is not listed, proceed to Question 17b, otherwise, skip to Question 18.***
17a	Other cancer clinical history	_____	7028280	Specify the other cancer type in the patient's clinical history.
17b	Other clinical history	_____	6690685	If not included in the previous list, specify other relevant prior diseases/disorders in the patient's clinical history.



Enrollment: Endometrium

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
18	Has the participant ever received hormone replacement therapy?	☐ Yes ☐ No ☐ Unknown	5206889	Indicate whether the patient has ever used hormone replacement therapy. ***Note: If the patient has received hormone replacement therapy, proceed to Question 19, otherwise, skip to Question 20.***
19	What type of hormone therapy was administered?	☐ Estrogen only ☐ Progesterone only ☐ Progesterone and Estrogen ☐ Unknown	3690502	Indicate the type of hormones the patient mainly used during that time.
20	Has the participant ever used oral contraceptives?	☐ Yes ☐ No ☐ Unknown	7028283	Indicate whether the patient has ever used oral contraceptives. ***Note: If the patient has used oral contraceptives, proceed to Question 21, otherwise, skip to Question 22.***
21	What type of oral contraceptives were used?	☐ Progestin only ☐ Progestin and estrogen ☐ Unknown	7028284	Indicate the type of oral contraceptive agent used.
Biospecimen Information				
22	Tissue sample type(s) collected for HCMI for this case	☐ Normal tissue ☐ Primary tumor ☐ Metastatic ☐ Recurrent ☐ Other tissue	2006911	Please select all the tissue sample types submitted for HCMI with this case.
23	Number of NORMAL tissues biospecimens collected for HCMI for this case	_____	6584256	Please provide the number of normal tissue specimens obtained for HCMI for this case. ***Note: This number is expected to be 1.***
24	Number of PRIMARY cancer tissue biospecimens collected for HCMI model development for this case	_____	6584257	Please provide the number of primary tumor specimens obtained for HCMI for this case. ***Note: A single primary tumor biospecimen obtained that is portioned for both sequencing and model generation counts as 1 single primary tumor specimen. This number is expected to be 1.***
25	Number of METASTATIC/RECURRENT cancer tissue biospecimens collected for HCMI model development for this case	_____	6584258	Please provide the number of metastatic and/or recurrent cancer biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
26	Number of OTHER tissue biospecimens collected for HCMI model development for this case	_____	6584259	Please provide the number of pre-malignant, non-malignant, or dysplastic tissue biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***



Enrollment: Endometrium

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
27	Total number of tissue biospecimens collected for HCMI for this case	_____	6584271	Please provide the total number of tissue biospecimens collected for HCMI for this case. ***Note: This number should be the sum of the normal, primary tumor, metastatic/recurrent tumor, and other biospecimen counts above.***
Normal Control Information				
28	Normal tissue biospecimen ordinal	_____	6584264	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
29	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
30	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
31	Type of normal control	☐ Whole blood ☐ Buccal cells ☐ Buffy coat ☐ Lymphocytes ☐ Extracted DNA from blood ☐ Extracted DNA from saliva ☐ Extracted DNA from buccal cells ☐ Extracted DNA from normal tissue ☐ FFPE non-neoplastic tissue ☐ Non-neoplastic tissue	3081936	Indicate the type of normal control submitted for this case.
32	Anatomic site of normal tissue	☐ Right ovary ☐ Left ovary ☐ Right fallopian tube ☐ Left fallopian tube ☐ Right tubo-ovarian ☐ Left tubo-ovarian ☐ Lower uterine segment ☐ Skin ☐ Other (specify) ☐ Not applicable	4132152	If non-neoplastic tissue was submitted as the normal control, select the anatomic site of the normal tissue. ***Note: If the anatomic site of normal tissue is not listed, proceed to Question 32a, otherwise, skip to Question 33.***
32a	Other anatomic site of normal tissue	_____	3288189	If non-neoplastic tissue, adjacent tissue, or normal tissue from another anatomic site was submitted as the normal control, provide the anatomic site of the normal tissue.
33	Distance from tumor to normal control tissue (if not blood)	☐ Adjacent (< or = 2cm) ☐ Distal (>2cm) ☐ Unknown ☐ Not applicable	3088708	Indicate the distance from the site of normal tumor collection to the primary tumor. ***Note: If normal tissue was not submitted, select 'Not applicable'.***
34	Normal tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the normal tissue sample collected for molecular characterization.
Primary Tumor Biospecimen Information				
35	ICD-10 code for primary tumor	☐ C54.0 ☐ C54.1 ☐ C54.2 ☐ C54.3 ☐ C54.8 ☐ C54.9 ☐ Other (specify)	3226287	Provide the ICD-10 code for the primary tumor as used to generate the ID3 for this subject. ***Note: If the ICD-10 code is not listed, proceed to 35a, otherwise, skip to Question 36.***



Enrollment: Endometrium

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
35a	Other ICD-10 code for primary tumor	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.
36	Tumor morphology	☐ 8263/3 ☐ 8380/3 ☐ 8382/3 ☐ 8383/3 ☐ 8570/3 ☐ 8930/3 ☐ 8931/3 ☐ 8933/3 ☐ 8890/3 ☐ 8891/3 ☐ 8896/3 ☐ 8900/3 ☐ 8714/3 ☐ 8805/3 ☐ 8441/3 ☐ 8980/3 ☐ 8480/3 ☐ 8013/3 ☐ 8041/3 ☐ 8020/3 ☐ Other (specify)	3226275	Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor. ***Note: If the ICD-O-3 histology code of the primary tumor is not listed, proceed to Question 36a, otherwise, skip to Question 37.***
36a	Specify other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.
37	Tissue or organ of origin	☐ Endometrium ☐ Uterus ☐ Other (specify)	3427536	Using the patient's pathology/laboratory report, select the primary site of the disease. ***Note: If the primary site of the disease is not listed, proceed to Question 37a, otherwise skip to Question 38.***
37a	Other tissue or organ of origin	_____	5946219	If the primary site of the disease is not included on the previous list, provide the primary site of the disease.
38	Histological type	☐ Endometrial cancer ☐ Uterine cancer ☐ Other (specify)	3081932	Select the surgical pathology text description of the histological tumor type. ***Note: If the histological tumor type is not listed, proceed to Question 38a, otherwise, skip to Question 39.***
38a	Other histological type	_____	3294805	If the traditional surgical pathology text description of the histological tumor type is not included on the previous list, please specify the histological type.
39	Histological subtype: endometrial carcinomas	☐ Endometrioid carcinoma, NOS ☐ Endometrioid carcinoma with squamous differentiation ☐ Endometrioid carcinoma, villoglandular variant ☐ Endometrioid carcinoma with secretory differentiation ☐ Endometrioid carcinoma, other variant (specify) ☐ Serous endometrial intraepithelial carcinoma ☐ Serous carcinoma ☐ Carcinosarcoma (malignant mixed Müllerian tumor) ☐ Mucinous carcinoma ☐ Clear cell carcinoma ☐ Small cell neuroendocrine carcinoma ☐ Large cell neuroendocrine carcinoma ☐ Mixed cell carcinoma (specify types and percentages) ☐ Undifferentiated carcinoma	3081934	Using the patient's pathology/laboratory report, select the histological subtype of the primary tumor. ***Note: If "Endometrioid carcinoma, other variant" is selected, proceed to Question 39a. If "Mixed cell carcinoma" is selected, proceed to Question 39b-c. If the histological subtype is not listed, proceed to Question 39d, otherwise, skip to Question 40.***



Enrollment: Endometrium

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

		☐ De-differentiated carcinoma ☐ Other (specify)		
39a	Specify the other endometrioid carcinoma variant	_____	7029865	If not provided in the previous list, specify the endometrioid adenocarcinoma variant histologic subtypes present.
39b	Specify mixed cell carcinoma types	_____	7029863	Specify the endometrial mixed cell adenocarcinoma histologic subtypes present.
39c	Specify mixed cell carcinoma percentages	_____	7029864	Specify the percentages present of the endometrial mixed cell adenocarcinoma histologic subtypes.
39d	Other histological subtype	_____	3124492	If the histological subtype for the primary tumor is not included in the provided list, specify the histological subtype.
40	Histological subtype: uterine sarcomas	☐ Leiomyosarcoma ☐ Leiomyosarcoma, epithelioid type ☐ Leiomyosarcoma, myxoid type ☐ Endometrial stromal sarcoma ☐ Endometrial stromal sarcoma with smooth muscle differentiation ☐ Endometrial stromal sarcoma with sex cord elements ☐ Endometrial stromal sarcoma with glandular elements ☐ Undifferentiated uterine/endometrial sarcoma ☐ Adenosarcoma ☐ Adenosarcoma with rhabdomyoblastic differentiation ☐ Adenosarcoma with cartilaginous differentiation ☐ Adenosarcoma with osseous differentiation ☐ Adenosarcoma with other heterologous element (specify) ☐ Adenosarcoma with sarcomatous overgrowth ☐ Endometrial rhabdomyosarcoma ☐ Malignant perivascular epithelioid cell tumor ☐ Other (specify)	3081934	Provide the traditional surgical pathology text description of the histological tumor subtype. ***Note: If "Adenosarcoma with other heterologous element" is selected, proceed to Question 40a. If the histological subtype is not listed, proceed to Question 40b, otherwise, skip to Question 41.***
40a	Specify the other heterologous element	_____	7029866	Specify the other heterologous elements present in the endometrioid adenocarcinoma histologic subtype.
40b	Other histological subtype: uterine sarcomas	_____	3124492	If not provided in the previous list, specify the traditional surgical pathology text description of the histological tumor subtype.
41	Prior malignancy (of the same cancer type)	☐ Yes ☐ No ☐ Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
42	Prior malignancy (other cancer type)	☐ Yes ☐ No ☐ Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.



Enrollment: Endometrium

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
43	AJCC cancer staging edition	☐ 1st ☐ 2nd ☐ 3rd ☐ 4th ☐ 5th ☐ 6th ☐ 7th ☐ 8th	2722309	Select the AJCC staging handbook edition used to stage the patient's primary tumor.
44	AJCC pathologic spread: Primary tumor (pT)	☐ TX ☐ T0 ☐ T1 ☐ T1a ☐ T1b ☐ T1c ☐ T2 ☐ T2a ☐ T2b ☐ T3 ☐ T3a ☐ T3b ☐ T4	3045435	Using the patient's pathology/ laboratory report, select the code for the pathologic T (primary tumor) as defined by the American Joint Committee on Cancer (AJCC).
45	AJCC pathologic spread: Lymph nodes (pN)	☐ NX ☐ N0 ☐ N0(i+) ☐ N1 ☐ N1mi ☐ N1a ☐ N2 ☐ N2mi ☐ N2a	3203106	Using the patient's pathology/ laboratory report, select the code for the pathologic N (nodal) as defined by the American Joint Committee on Cancer (AJCC).
46	AJCC pathologic spread: Distant metastases (pM)	☐ MX ☐ M1	3045439	Using the patient's pathology/ laboratory report, select the code for the pathologic M (metastasis) as defined by the American Joint Committee on Cancer (AJCC).
47	Tumor stage (pathological)	☐ Stage I ☐ Stage IA ☐ Stage IB ☐ Stage II ☐ Stage III ☐ Stage IIIA ☐ Stage IIIB ☐ Stage IIIC ☐ Stage IIIC1 ☐ Stage IIIC2 ☐ Stage IVA ☐ Stage IVB	3065862	Using the patient's pathology/ laboratory report, in conjunction with the patient's medical record, select the stage as defined by the American Joint Committee on Cancer (AJCC).
48	FIGO Stage	☐ Stage I ☐ Stage IA ☐ Stage IB ☐ Stage II ☐ Stage IIA ☐ Stage IIB ☐ Stage III ☐ Stage IIIA ☐ Stage IIIB ☐ Stage IIIC ☐ Stage IIIC1 ☐ Stage IIIC2 ☐ Stage IV ☐ Stage IVA ☐ Stage IVB	5326898	Using the patient's pathology /laboratory report, in conjunction with the patient's medical record, select the stage as defined by the Federation of Gynecology and Obstetrics (FIGO), 2014 edition.
49	FIGO grade (applies to endometrioid and mucinous carcinomas only)	☐ Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Other (specify) ☐ Cannot be assessed ☐ Not applicable	7028262	Select the grade representing the extent of endometrial cancer in the body, based on staging criteria from the Federation of Gynecology and Obstetrics (FIGO). ***Note: If the FIGO grade is not listed, proceed to Question 49a, otherwise, skip to Question 50.***
49a	Specify other FIGO grade	_____	7028262	If not included in the previous list, provide the grade representing the extent of endometrial cancer in the body, based on staging criteria from the Federation of Gynecology and Obstetrics (FIGO).
50	Histologic grade (applies to sarcomas only)	☐ Low grade ☐ High grade ☐ With sarcomatous overgrowth ☐ Cannot be assessed ☐ Not applicable	7028298	Select the grade representing the extent of endometrioid stroma sarcoma in the body.
Prognostic/Predictive/Lifestyle Features for Primary Tumor Prognosis or Responsiveness to Treatment				
51	Specimen integrity	☐ Intact ☐ Opened ☐ Mocellated ☐ Other (specify)	2783662	Indicate the physical status of the specimen. ***Note: If the specimen integrity is not listed, proceed to Question 51a, otherwise, skip to Question 52.***
51a	Specify specimen integrity	_____	7028264	If not included in the previous list, specify the physical condition of the specimen.



Enrollment: Endometrium

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
52	Is there myometrial invasion?	☐ Yes ☐ No ☐ Unknown	3440922	Indicate whether tumor cells have invaded the myometrium. ***Note: If myometrial invasion is present, proceed to Question 53, otherwise, skip to Question 56.***
53	Myometrial invasion depth (mm)	_____mm	7028265	Indicate the depth (in mm) of invasion of the myometrium by cancer.
54	Myometrial thickness (mm)	_____mm	3440923	Provide the greatest depth of the myometrial invasion as a percentage of the thickness of the involved wall.
55	Percentage of myometrial invasion	_____%	3440923	Provide the greatest depth of the myometrial invasion as a percentage of the thickness of the involved wall.
56	Tumor size, largest dimension	_____cm	64215	Provide the largest dimension of the primary tumor in cm, regardless of anatomical plane.
57	Adenomyosis	☐ Not identified ☐ Present, uninvolved by carcinoma ☐ Present, involved by carcinoma ☐ Cannot be determined	7028267	Indicate whether or not the growth of endometrial tissue inside the muscular wall of the uterine corpus is involved with endometrial cancer.
58	Uterine serosa involvement	☐ Yes ☐ No ☐ Cannot be determined	7024271	Indicate whether or not the uterine serosa (perimetrium) is involved in the disease.
59	Lower uterine segment involvement	☐ Not identified ☐ Present, superficial (non-myoinvasive) ☐ Present, myoinvasive ☐ Cannot be determined	7028268	Indicate whether the isthmus uteri has been involved with endometrial cancer.
60	Cervical stromal involvement	☐ Present ☐ Not identified ☐ Cannot be determined	7028269	Indicate whether or not the cervix uteri stromal cells are involved with endometrial cancer.
61	Other tissue/organ involvement	☐ Not applicable ☐ Not identified ☐ Right ovary ☐ Left ovary ☐ Ovary (side not specified) ☐ Right fallopian tube ☐ Left fallopian tube ☐ Fallopian tube (side not specified) ☐ Vagina ☐ Right parametrium ☐ Left parametrium ☐ Parametrium (side not specified) ☐ Pelvic wall ☐ Bladder wall ☐ Bladder mucosa ☐ Rectal wall ☐ Bowel mucosa ☐ Omentum ☐ Pelvic lymph node(s) ☐ Peri-aortic lymph node(s) ☐ Other organ/tissue (specify) ☐ Cannot be determined	2793699	Select all sites of other tissue/organ involvement. This does not include the primary tumor site. ***Note: If the other tissue/organ involved is not listed, proceed to Question 61a, otherwise, skip to Question 62.***
61a	Specify other tissue/organ involvement	_____	7029867	If not included in the previous list, specify the other site of other tissue/organ involvement. This does not include the primary tumor site.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
62	Peritoneal/Ascitic fluid	☐ Not submitted/unknown ☐ Negative for malignancy (normal/benign) ☐ Atypical and/or suspicious ☐ Malignant (positive for malignancy) ☐ Unsatisfactory/nondiagnostic	6690681	Indicate the outcome of cytological analysis for peritoneal/ascitic fluid.
63	Lymphovascular invasion	☐ Present ☐ Absent ☐ Cannot be determined	64727	Indicate whether large vessel (vascular) invasion or small, thin-walled (lymphatic) invasion was detected in the tumor specimen.
64	Lymph nodes	☐ No lymph nodes submitted or found ☐ All lymph nodes negative for tumor cells ☐ Positive lymph nodes	7028287	Indicate whether the lymph nodes are involved with endometrial cancer as determined by pathologic assessment. ***Note: If lymph nodes are positive, proceed to Question 65, otherwise, skip to Question 75.***
65	Number of pelvic nodes with micrometastases	_____	7028289	Indicate the number of pelvic lymph nodes that have micrometastases present.
66	Number of pelvic nodes with macrometastases	_____	7028288	Indicate the number of pelvic lymph nodes that have macrometastases present.
67	Number of pelvic nodes with isolated tumor cells	_____	7028290	Indicate the number of pelvic lymph nodes that have isolated tumor cells present.
68	Total number of pelvic nodes examined	_____	7028294	Indicate the total number of pelvic lymph nodes assessed for the presence of metastases and/or tumor cells.
69	Number of pelvic sentinel nodes examined	_____	7028295	Indicate the total number of pelvic sentinel lymph nodes assessed for the presence of metastases and/or tumor cells.
70	Number of para-aortic nodes with micrometastases	_____	7028292	Indicate the number of para-aortic lymph nodes that have micrometastases present.
71	Number of para-aortic nodes with macrometastases	_____	7028291	Indicate the number of para-aortic lymph nodes that have macrometastases present.
72	Number of para-aortic nodes with isolated tumor cells	_____	7028293	Indicate the total number of para-aortic lymph nodes that have isolated tumor cells present.
73	Total number of para-aortic nodes examined	_____	7028296	Indicate the total number of para-aortic lymph nodes assessed for the presence of metastases and/or tumor cells.
74	Number of para-aortic sentinel nodes examined	_____	7028297	Indicate the total number of para-aortic sentinel lymph nodes assessed for the presence of metastases and/or tumor cells.
75	Additional pathologic findings	☐ None identified ☐ Atypical hyperplasia/endometrial intraepithelial neoplasia (EIN) ☐ Other (specify)	7028278	Indicate additional pathologic findings present in the patient. ***Note: If the additional pathologic finding is not listed, proceed to Question 75a, otherwise, skip to Question 76.***
75a	Specify additional pathologic findings	_____	7028279	If not included in the previous list, specify any additional pathologic findings.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
76	Residual tumor	☐ R0 ☐ R1 ☐ R2 ☐ RX ☐ Not evaluated	2608702	Indicate the status of a tissue margin following surgical resection.
77	Was ER IHC performed?	☐ Yes ☐ No ☐ Unknown	6062416	Indicate whether estrogen receptor (ER) expression was assessed by immunohistochemistry (IHC). ***Note: If ER IHC was performed, proceed to Question 78, otherwise, skip to Question 79.***
78	ER expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6690720	Indicate the status of estrogen receptor (ER) protein expression as determined by immunohisto-chemistry (IHC).
79	Was PR IHC performed?	☐ Yes ☐ No ☐ Unknown	6062504	Indicate whether progesterone receptor (PR) expression was assessed by immunohistochemistry (IHC). ***Note: If PR IHC was performed, proceed to Question 80, otherwise, skip to Question 81.***
80	PR expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063673	Indicate the status of progesterone receptor (PR) protein expression as determined by immunohistochemistry (IHC).
81	Was HER2 IHC performed?	☐ Yes ☐ No ☐ Unknown	6063454	Indicate whether HER2 expression was assessed by immunohisto-chemistry (IHC). ***Note: If HER2 IHC was performed, proceed to Question 82, otherwise, skip to Question 83.***
82	HER2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	2957563	Indicate the expression of HER2 as assessed by immunohistochemistry (IHC).
83	Was HER2 FISH/CISH performed?	☐ Yes ☐ No ☐ Unknown	6063447	Indicate whether HER2 was assessed by fluorescence in situ hybridization (FISH) or chromogenic in situ hybridization (CISH). ***Note: If HER2 FISH/CISH was performed, proceed to Question 84, otherwise, skip to Question 85.***
84	HER2 status by FISH/CISH	☐ Amplified ☐ Not amplified ☐ Equivocal	2854089	Select the HER2 status as assessed by FISH/CISH.
85	Was MLH1 IHC performed?	☐ Yes ☐ No ☐ Unknown	6062411	Indicate whether MLH1 expression was assessed by immunohisto-chemistry (IHC). ***Note: If MLH1 IHC was performed, proceed to Question 86, otherwise, skip to Question 87.***
86	MLH1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063668	Indicate the status of MLH1 protein expression as determined by immunohistochemistry (IHC).
87	MLH1 promoter methylation status	☐ MLH1 promoter hypermethylation present ☐ MLH1 promoter hypermethylation absent ☐ MLH1 promoter hypermethylation not assessed ☐ Cannot be determined	6033150	Indicate the methylation status of the MLH1 promoter.
88	Was MSH2 IHC performed?	☐ Yes ☐ No ☐ Unknown	6062412	Indicate whether MSH2 expression was assessed by immunohisto-chemistry (IHC). ***Note: If MSH2 IHC was performed, proceed to Question 89, otherwise, skip to Question 90.***



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
89	MSH2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063669	Indicate the status of MSH2 protein expression as determined by immunohistochemistry (IHC).
90	Was PMS2 IHC performed?	☐ Yes ☐ No ☐ Unknown	6062413	Indicate whether PMS2 expression was assessed by immunohisto-chemistry (IHC). ***Note: If PMS2 IHC was performed, proceed to Question 91, otherwise, skip to Question 92.***
91	PMS2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063670	Indicate the status of PMS2 protein expression as determined by immunohistochemistry (IHC).
92	Was MSH6 IHC performed?	☐ Yes ☐ No ☐ Unknown	6062414	Indicate whether MSH6 expression was assessed by immunohisto-chemistry (IHC). ***Note: If MSH6 IHC was performed, proceed to Question 93, otherwise, skip to Question 94.***
93	MSH6 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063671	Indicate the status of MSH6 protein expression as determined by immunohistochemistry (IHC).
94	Microsatellite instability	☐ Stable ☐ Low ☐ High ☐ Equivocal	6032776	Indicate the status of the tumor for microsatellite instability. (High at ≥30% loci tested, low at 1%-29% loci tested.)
95	Was p53 IHC performed?	☐ Yes ☐ No ☐ Unknown	6690705	Indicate whether p53 expression was assessed by immunohisto-chemistry (IHC). ***Note: If p53 IHC was performed, proceed to Question 96, otherwise, skip to Question 97.***
96	p53 expression by IHC	☐ Normal ☐ Abnormal strong diffuse overexpression (>90%) ☐ Abnormal null expression (complete loss of expression) ☐ Cannot be determined	6690719	Indicate the status of p53 protein expression as determined by immunohistochemistry (IHC).
97	Was p16 IHC performed?	☐ Yes ☐ No ☐ Unknown	6690713	Indicate whether p16 expression was assessed by immunohisto-chemistry (IHC). ***Note: If p16 IHC was performed, proceed to Question 98, otherwise, skip to Question 99.***
98	p16 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6690724	Indicate the status of p16 protein expression as determined by immunohistochemistry (IHC).
99	Mismatch repair status	☐ Evidence of MMR mutation by sequencing ☐ Evidence of MMR protein loss by IHC ☐ MMR loss evidence hypermutation phenotype (>10 mutations/Mb) ☐ No evidence of MMR alteration	6002208	Indicate the mismatch repair gene status.
100	Was PTEN IHC performed?	☐ Yes ☐ No ☐ Unknown	6062415	Indicate whether PTEN expression was assessed by immunohistochemistry (IHC).
101	PTEN expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063672	Indicate the status of PTEN protein expression as determined by immunohistochemistry (IHC).
102	Was PTEN mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063446	Indicate whether PTEN mutation analysis was performed. ***Note: If PTEN mutation analysis was performed, proceed to Question 103, otherwise, skip to Question 105.***



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
103	Was a mutation in PTEN identified?	☐ Yes ☐ No	6063529	Indicate whether a mutation in PTEN was identified through mutation analysis. ***Note: if a PTEN mutation was identified, proceed to Question 104, otherwise, skip to Question 105.***
104	If PTEN mutation identified, which one?	☐ R130G ☐ R130Q ☐ R130L ☐ R130P ☐ Other (specify)	6063736	Indicate the mutation identified for the PTEN gene. ***Note: If the PTEN mutation is not listed, proceed to Question 104a, otherwise, skip to Question 105.***
104a	Other PTEN mutation	_____	6816076	If the specific mutation of the PTEN gene identified was not included in the previous list, please specify the mutation
105	Was PIK3CA mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063445	Indicate whether PIK3CA mutation analysis was performed. ***Note: If PIK3CA mutation analysis was performed, proceed to Question 106, otherwise, skip to Question 108.***
106	Was a mutation in PIK3CA identified?	☐ Yes ☐ No	6063524	Indicate whether a mutation in PIK3CA was identified through mutation analysis. ***Note: If a PIK3CA mutation was identified, proceed to Question 107, otherwise, skip to Question 108.***
107	If PIK3CA mutation identified, which one?	☐ R88Q ☐ E542K ☐ E542A ☐ E542Q ☐ E542V ☐ E545K ☐ E545D ☐ E545A ☐ E545G ☐ E545Q ☐ H1047R ☐ H1047L ☐ H1047Y ☐ H1047Q ☐ Other (specify)	7028281	Indicate the mutation identified for the PIK3CA gene. ***Note: If the PIK3CA mutation is not listed, proceed to Question 107a, otherwise, skip to Question 108.***
107a	Other PIK3CA mutation	_____	7028282	If the specific mutation of the PIK3CA gene identified was not included in the previous list, please specify the mutation.
108	Was TP53 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063448	Indicate whether TP53 mutation analysis was performed. ***Note: If TP53 mutation analysis was performed, proceed to Question 109, otherwise, skip to Question 111.***
109	Was a mutation in TP53 identified?	☐ Yes ☐ No	6063523	Indicate whether a mutation in TP53 was identified through mutation analysis. ***Note: If a TP53 mutation was identified, proceed to Question 110, otherwise, skip to Question 111.***
110	If TP53 mutation identified, which one?	☐ R273H ☐ R273C ☐ R273S ☐ R273L ☐ R248Q ☐ R248W ☐ R175H ☐ R175C ☐ Other (specify)	7028281	Indicate the mutation identified for the TP53 gene. ***Note: If the TP53 mutation is not listed, proceed to Question 110a, otherwise, skip to Question 111.***
110a	Other TP53 mutation	_____	6101683	If the specific mutation of the TP53 gene identified was not included in the previous list, please specify the mutation.
Primary Tumor Sample Information				
111	Are you submitting a primary tumor tissue sample for this case?	☐ Yes ☐ No		***If yes, proceed to question 112.*** ***If submitting a metastatic/recurrent tumor biospecimen, proceed to Question 140.***



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
112	Primary tumor biospecimen ordinal	_____	6584265	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number should be "1".***
113	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
114	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
115	Sample represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this primary tumor specimen represent the PRIMARY DIAGNOSIS for this Case ID3? ***Note: If no, proceed to Question 116, otherwise, skip to Question 117.***
116	Specify the ICD-10 code	_____	3226287	Provide the ICD-10 code for the primary tumor used to generate the model submitted to HCMI.
117	Tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the tumor tissue sample collected for molecular characterization.
118	Anatomic site from which the tumor was obtained	☐ Endometrium ☐ Lower uterine segment ☐ Endometrial polyp ☐ Adenomyosis ☐ Other (specify)	4214629	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI. ***Note: If the tissue or organ not listed, proceed to Question 118a. Otherwise, skip to Question 119.***
118a	Other anatomic site from which the tumor was obtained	_____	5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.
119	Method of cancer sample procurement	☐ Total hysterectomy and bilateral salpingo-oophorectomy ☐ Radical hysterectomy ☐ Simple hysterectomy ☐ Supracervical hysterectomy ☐ Endometrial biopsy ☐ Hysteroscopy ☐ Dilation and curettage (D&C) ☐ Other (specify)	3103514	Provide the procedure performed to obtain the primary tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 119a, otherwise, skip to Question 120.***
119a	Specify the other method of tumor sample procurement	_____	2006730	Specify the procedure performed to obtain the primary tumor tissue, if not included in the previous list.
120	Number of days from index date to date of tumor sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the tumor tissue submitted for HCMI.
121	Tumor tissue type	☐ Primary ☐ Additional Primary ☐ NOS	3288124	Provide the primary tumor tissue type for this sample.
Primary Tumor Model Information				
122	Primary model biospecimen ordinal	_____	6594596	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number is expected to be "1".***



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
123	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
124	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
125	Model represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this model represent the primary diagnosis for this Case ID3?
126	Model's primary tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the PRIMARY TUMOR TISSUE from which this model is derived.
127	Model's primary tumor biospecimen ordinal	_____	6584265	Enter the biospecimen ordinal of the PRIMARY TUMOR TISSUE from which this model is derived.
Treatment Information				
128	History of neoadjuvant treatment	☐ No ☐ Yes; radiation prior to resection ☐ Yes; pharmaceutical treatment prior to resection ☐ Yes; both radiation and pharmaceutical treatment prior to resection ☐ Unknown	3382737	Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment. ***Note: Pharmaceutical therapy is addressed in Questions 129-137. Radiation therapy is addressed in Questions 138-139.***
129	Neoadjuvant chemotherapy type	☐ Cytotoxic chemotherapy ☐ Hormonal ☐ Immunotherapy (cellular and immune checkpoint) ☐ Targeted therapy (small molecule inhibitors and targeted antibodies) ☐ Not applicable	5832928	Select all neoadjuvant chemotherapy types that were administered to the patient. ***Note: Cytotoxic chemotherapy is addressed in Questions 130-131. Hormone therapy is addressed in Questions 132-133. Immunotherapy is addressed in Questions 134-135. Targeted therapy is addressed in Questions 136-137.***
130	Neoadjuvant chemotherapeutic regimen	☐ Doxorubicin ☐ Liposomal doxorubicin ☐ Cisplatin ☐ Paclitaxel ☐ Carboplatin ☐ Ifosfamide ☐ Etoposide ☐ Gemcitabine ☐ Docetaxel ☐ Other (specify)	2853313	Select all chemotherapeutics used for neoadjuvant therapy. ***Note: If neoadjuvant chemotherapy was not given, skip to Question 132. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 130a, otherwise, skip to Question 131.***
130a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapies administered.
131	Days to neoadjuvant chemotherapy treatment from index date	_____	5102411	Provide the number of days from index date to the date of treatment with neoadjuvant chemotherapy.
132	Hormone therapy	☐ Medroxyprogesterone acetate ☐ Megestrol acetate ☐ Tamoxifen ☐ Goserelin ☐ Leuprolide ☐ Letrozole ☐ Anastrozole ☐ Exemestane ☐ Progestational IUD ☐ Other (specify)	7028259	Select the hormone therapy administered to the patient. ***Note: If hormone therapy was not administered, skip to Question 134. If the hormone therapy is not listed, proceed to Question 132a, otherwise, skip to Question 133.***
132a	Other hormone therapy	_____	2405358	If the hormone therapy is not included in the provided list, specify hormone therapy.
133	Days to hormone therapy treatment from index date	_____	5102411	Provide the number of days from index date to the date of treatment with hormone therapy.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
134	Immunotherapy	☐ Filgrastim ☐ Other (specify)	7028261	Select the immunotherapy administered to the patient. ***Note: If immunotherapy was not administered, skip to Question 136. If the immunotherapy is not listed, proceed to Question 134a, otherwise, skip to Question 135.***
134a	Specify other immunotherapy	_____	2953828	Provide the name of the immunotherapy administered to the patient.
135	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
136	Targeted Therapy	☐ Bevacizumab ☐ Everolimus ☐ Ridaforolimus ☐ Other (specify)	7028260	Select the targeted therapy administered to the patient. ***Note: If targeted therapy was not administered, skip to Question 138. If the targeted therapy regimen is not listed, proceed to Question 136a, otherwise, skip to Question 137.***
136a	Specify targeted therapy	_____	4308476	Provide the name of the targeted therapy administered to the patient.
137	Days to targeted therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with targeted therapy.
138	Radiation therapy administered type	☐ 2D conventional ☐ 3D conformal ☐ Brachytherapy HDR ☐ Brachytherapy LDR ☐ IMRT ☐ Proton Beam ☐ Stereotactic Body RT ☐ Stereotactic Radiosurgery ☐ WBRT ☐ Other (specify) ☐ Unspecified ☐ Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. ***Note: If radiation therapy was not administered, proceed to Question 140. If the radiation therapy is not listed, proceed to Question 138a, otherwise, skip to Question 139.***
138a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
139	Days to radiation treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with radiation therapy.
Metastatic/Recurrent Tumor Biospecimen Information				
140	Are you submitting a metastatic/recurrent tumor tissue sample?	☐ Yes ☐ No		Indicate whether a metastatic/ recurrent tumor biospecimen was collected for this ID3 case. ***Note: If yes, proceed to Question 141. If submitting an OTHER tissue sample, proceed to Question 232.***
141	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1", the second should be number "2", etc.***
142	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
143	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
144	Metastatic/recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
145	Number of days from index date to date of diagnosis of metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic/recurrent disease.
146	Method of metastatic/ recurrent cancer sample procurement	☐ Total hysterectomy and bilateral salpingo-oophorectomy ☐ Radical hysterectomy ☐ Simple hysterectomy ☐ Supracervical hysterectomy ☐ Bilateral salpingo-oophorectomy ☐ Right salpingo-oophorectomy ☐ Left salpingo-oophorectomy ☐ Salpingo-oophorectomy, side not specified ☐ Right oophorectomy ☐ Left oophorectomy ☐ Bilateral salpingectomy ☐ Right salpingectomy ☐ Left salpingectomy ☐ Salpingectomy, side not specified ☐ Vaginal cuff resection ☐ Omentectomy ☐ Peritoneal biopsies ☐ Peritoneal washing ☐ Lymphadenectomy ☐ Core needle biopsy ☐ Fine needle aspirate ☐ Other Method (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 146a, otherwise, skip to Question 147.***
146a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
147	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
148	Metastatic/recurrent site	☐ Endometrium ☐ Lower uterine segment ☐ Pelvic recurrence ☐ Exta-abdominal lymph node(s) ☐ Peritoneum ☐ Lung ☐ Liver ☐ Adrenal gland ☐ Brain ☐ Bone ☐ Soft tissue ☐ Right ovary ☐ Left ovary ☐ Right fallopian tube ☐ Left fallopian tube ☐ Right tubo-ovarian ☐ Left tubo-ovarian ☐ Pelvic lymph node(s) ☐ Para-aortic lymph node(s) ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 148a, otherwise, skip to Question 149.***
148a	Other metastatic/ recurrent site	_____	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
149	Site of relapse	☐ Local ☐ Distant ☐ Regional ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
150	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
151	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
152	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
153	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
154	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
155	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
156	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
Prognostic/Predictive/Lifestyle Features for Metastatic/Recurrent Tumor Prognosis or Responsiveness to Treatment				
157	Other tissue/organ involvement	☐ Not applicable ☐ Not identified ☐ Right ovary ☐ Left ovary ☐ Ovary (side not specified) ☐ Right fallopian tube ☐ Left fallopian tube ☐ Fallopian tube (side not specified) ☐ Vagina ☐ Right parametrium ☐ Left parametrium ☐ Parametrium (side not specified) ☐ Pelvic wall ☐ Bladder wall ☐ Bladder mucosa ☐ Rectal wall ☐ Bowel mucosa ☐ Omentum ☐ Pelvic lymph node(s) ☐ Peri-aortic lymph node(s) ☐ Other organ/tissue (specify) ☐ Cannot be determined	2793699	Select all sites of other tissue/organ involvement. This does not include the primary tumor site.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
157a	Specify other tissue/organ involvement	_____	7029867	If not included in the previous list, specify the other site of other tissue/organ involvement. This does not include the primary tumor site.
158	Peritoneal/Ascitic fluid	☐ Not submitted/unknown ☐ Negative for malignancy (normal/benign) ☐ Atypical and/or suspicious ☐ Malignant (positive for malignancy) ☐ Unsatisfactory/nondiagnostic	6690681	Indicate the outcome of cytological analysis for peritoneal/ascitic fluid.
159	Lymph nodes	☐ No lymph nodes submitted or found ☐ All lymph nodes negative for tumor cells ☐ Positive lymph nodes	7028287	Indicate whether the lymph nodes are involved with endometrial cancer as determined by pathologic assessment. ***Note: If lymph nodes are positive, proceed to Question 160, otherwise, skip to Question 170.***
160	Number of pelvic nodes with micrometastases	_____	7028289	Indicate the number of pelvic lymph nodes that have micrometastases present.
161	Number of pelvic nodes with macrometastases	_____	7028288	Indicate the number of pelvic lymph nodes that have macrometastases present.
162	Number of pelvic nodes with isolated tumor cells	_____	7028290	Indicate the number of pelvic lymph nodes that have isolated tumor cells present.
163	Total number of pelvic nodes examined	_____	7028294	Indicate the total number of pelvic lymph nodes assessed for the presence of metastases and/or tumor cells.
164	Number of pelvic sentinel nodes examined	_____	7028295	Indicate the total number of pelvic sentinel lymph nodes assessed for the presence of metastases and/or tumor cells.
165	Number of para-aortic nodes with micrometastases	_____	7028292	Indicate the number of para-aortic lymph nodes that have micrometastases present.
166	Number of para-aortic nodes with macrometastases	_____	7028291	Indicate the number of para-aortic lymph nodes that have macrometastases present.
167	Number of para-aortic nodes with isolated tumor cells	_____	7028293	Indicate the total number of para-aortic lymph nodes that have isolated tumor cells present.
168	Total number of para-aortic nodes examined	_____	7028296	Indicate the total number of para-aortic lymph nodes assessed for the presence of metastases and/or tumor cells.
169	Number of para-aortic sentinel nodes examined	_____	7028297	Indicate the total number of para-aortic sentinel lymph nodes assessed for the presence of metastases and/or tumor cells.
170	Residual tumor	☐ R0 ☐ R1 ☐ R2 ☐ RX ☐ Not evaluated	2608702	Indicate the status of a tissue margin following surgical resection.
171	Was ER IHC performed?	☐ Yes ☐ No ☐ Unknown	6062416	Indicate whether estrogen receptor (ER) expression was assessed by immunohistochemistry (IHC). ***Note: If ER IHC was performed, proceed to Question 172, otherwise, skip to Question 173.***



Enrollment: Endometrium

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
172	ER expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6690720	Indicate the status of estrogen receptor (ER) protein expression as determined by immunohisto-chemistry (IHC).
173	Was PR IHC performed?	☐ Yes ☐ No ☐ Unknown	6062504	Indicate whether progesterone receptor (PR) expression was assessed by immunohistochemistry (IHC). ***Note: If PR IHC was performed, proceed to Question 174, otherwise, skip to Question 175.***
174	PR expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063673	Indicate the status of progesterone receptor (PR) protein expression as determined by immunohistochemistry (IHC).
175	Was HER2 IHC performed?	☐ Yes ☐ No ☐ Unknown	6063454	Indicate whether HER2 expression was assessed by immunohisto-chemistry (IHC). ***Note: If HER2 IHC was performed, proceed to Question 176, otherwise, skip to Question 177.***
176	HER2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	2957563	Indicate the expression of HER2 as assessed by immunohistochemistry (IHC).
177	Was HER2 FISH/CISH performed?	☐ Yes ☐ No ☐ Unknown	6063447	Indicate whether HER2 was assessed by fluorescence in situ hybridization (FISH) or chromogenic in situ hybridization (CISH). ***Note: If HER2 FISH/CISH was performed, proceed to Question 178, otherwise, skip to Question 179.***
178	HER2 status by FISH/CISH	☐ Amplified ☐ Not amplified ☐ Equivocal	2854089	Select the HER2 status as assessed by FISH/CISH.
179	Was MLH1 IHC performed?	☐ Yes ☐ No ☐ Unknown	6062411	Indicate whether MLH1 expression was assessed by immunohistochemistry (IHC). ***Note: If MLH1 IHC was performed, proceed to Question 180, otherwise, skip to Question 181.***
180	MLH1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063668	Indicate the status of MLH1 protein expression as determined by immunohistochemistry (IHC).
181	MLH1 promoter methylation status	☐ MLH1 promoter hypermethylation present ☐ MLH1 promoter hypermethylation absent ☐ MLH1 promoter hypermethylation not assessed ☐ Cannot be determined	6033150	Indicate the methylation status of the MLH1 promoter.
182	Was MSH2 IHC performed?	☐ Yes ☐ No ☐ Unknown	6062412	Indicate whether MSH2 expression was assessed by immunohistochemistry (IHC). ***Note: If MSH2 IHC was performed, proceed to Question 183, otherwise, skip to Question 184.***
183	MSH2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063669	Indicate the status of MSH2 protein expression as determined by immunohistochemistry (IHC).
184	Was PMS2 IHC performed?	☐ Yes ☐ No ☐ Unknown	6062413	Indicate whether PMS2 expression was assessed by immunohisto-chemistry (IHC). ***Note: If PMS2 IHC was performed, proceed to Question 185, otherwise, skip to Question 186.***



Enrollment: Endometrium

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
185	PMS2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063670	Indicate the status of PMS2 protein expression as determined by immunohistochemistry (IHC).
186	Was MSH6 IHC performed?	☐ Yes ☐ No ☐ Unknown	6062414	Indicate whether MSH6 expression was assessed by immunohisto-chemistry (IHC). ***Note: If MSH6 IHC was performed, proceed to Question 187, otherwise, skip to Question 188.***
187	MSH6 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063671	Indicate the status of MSH6 protein expression as determined by immunohistochemistry (IHC).
188	Microsatellite instability	☐ Stable ☐ Low ☐ High ☐ Equivocal	6032776	Indicate the status of the tumor for microsatellite instability. (High at ≥30% loci tested, low at 1%-29% loci tested.)
189	Was p53 IHC performed?	☐ Yes ☐ No ☐ Unknown	6690705	Indicate whether p53 expression was assessed by immunohisto-chemistry (IHC). ***Note: If p53 IHC was performed, proceed to Question 190, otherwise, skip to Question 191.***
190	p53 expression by IHC	☐ Normal ☐ Abnormal strong diffuse overexpression (>90%) ☐ Abnormal null expression (complete loss of expression) ☐ Cannot be determined	6690719	Indicate the status of p53 protein expression as determined by immunohistochemistry (IHC).
191	Was p16 IHC performed?	☐ Yes ☐ No ☐ Unknown	6690713	Indicate whether p16 expression was assessed by immunohisto-chemistry (IHC). ***Note: If p16 IHC was performed, proceed to Question 192, otherwise, skip to Question 193.***
192	p16 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6690724	Indicate the status of p16 protein expression as determined by immunohistochemistry (IHC).
193	Mismatch repair status	☐ Evidence of MMR mutation by sequencing ☐ Evidence of MMR protein loss by IHC ☐ MMR loss evidence hypermutation phenotype (>10 mutations/Mb) ☐ No evidence of MMR alteration	6002208	Indicate the mismatch repair gene status.
194	Was PTEN IHC performed?	☐ Yes ☐ No ☐ Unknown	6062415	Indicate whether PTEN expression was assessed by immunohisto-chemistry (IHC).
195	PTEN expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063672	Indicate the status of PTEN protein expression as determined by immunohistochemistry (IHC).
196	Was PTEN mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063446	Indicate whether PTEN mutation analysis was performed. ***Note: If PTEN mutation analysis was performed, proceed to Question 197, otherwise, skip to Question 199.***
197	Was a mutation in PTEN identified?	☐ Yes ☐ No	6063529	Indicate whether a mutation in PTEN was identified through mutation analysis. ***Note: if a PTEN mutation was identified, proceed to Question 198, otherwise, skip to Question 199.***
198	If PTEN mutation identified, which one?	☐ R130G ☐ R130P ☐ R130Q ☐ Other (specify) ☐ R130L	6063736	Indicate the mutation identified for the PTEN gene. ***Note: If the PTEN mutation is not listed, proceed to Question 198a, otherwise, skip to Question 199.***



Enrollment: Endometrium

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
198a	Other PTEN mutation	_____	6816076	If the specific mutation of the PTEN gene identified was not included in the previous list, please specify the mutation.
199	Was PIK3CA mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063445	Indicate whether PIK3CA mutation analysis was performed. ***Note: If PIK3CA mutation analysis was performed, proceed to Question 200, otherwise, skip to Question 202.***
200	Was a mutation in PIK3CA identified?	☐ Yes ☐ No	6063524	Indicate whether a mutation in PIK3CA was identified through mutation analysis. ***Note: If a PIK3CA mutation was identified, proceed to Question 201, otherwise, skip to Question 202.***
201	If PIK3CA mutation identified, which one?	☐ R88Q ☐ E542K ☐ E542A ☐ E542Q ☐ E542V ☐ E545K ☐ E545D ☐ E545A ☐ E545G ☐ E545Q ☐ H1047R ☐ H1047L ☐ H1047Y ☐ H1047Q ☐ Other (specify)	7028281	Indicate the mutation identified for the PIK3CA gene. ***Note: If the PIK3CA mutation is not listed, proceed to Question 201a, otherwise, skip to Question 202.***
201a	Other PIK3CA mutation	_____	7028282	If the specific mutation of the PIK3CA gene identified was not included in the previous list, please specify the mutation.
202	Was TP53 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063448	Indicate whether TP53 mutation analysis was performed. ***Note: If TP53 mutation analysis was performed, proceed to Question 203, otherwise, skip to Question 205.***
203	Was a mutation in TP53 identified?	☐ Yes ☐ No	6063523	Indicate whether a mutation in TP53 was identified through mutation analysis. ***Note: If a TP53 mutation was identified, proceed to Question 204, otherwise, skip to Question 205.***
204	If TP53 mutation identified, which one?	☐ R273H ☐ R273C ☐ R273S ☐ R273L ☐ R248Q ☐ R248W ☐ R175H ☐ R175C ☐ Other (specify)	7028281	Indicate the mutation identified for the TP53 gene. ***Note: If the TP53 mutation is not listed, proceed to Question 204a, otherwise, skip to Question 205.***
204a	Other TP53 mutation	_____	6101683	If the specific mutation of the TP53 gene identified was not included in the previous list, please specify the mutation.
Additional Metastatic/Recurrent Tumor Biospecimen Information (if applicable)				
205	Are you submitting an additional metastatic/ recurrent tumor tissue sample?	☐ Yes ☐ No		A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen. ***Note: If yes, proceed to Question 206, otherwise, skip to Question 222.***



Enrollment: Endometrium

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
206	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. The first biospecimen should be number "1," the second should be number "2," etc.
207	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
208	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
209	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
210	Number of days from index date to date of diagnosis of additional metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of additional metastatic/recurrent disease.
211	Method of metastatic/ recurrent cancer sample procurement	☐ Total hysterectomy and bilateral salpingo-oophorectomy ☐ Radical hysterectomy ☐ Simple hysterectomy ☐ Supracervical hysterectomy ☐ Bilateral salpingo-oophorectomy ☐ Right salpingo-oophorectomy ☐ Left salpingo-oophorectomy ☐ Salpingo-oophorectomy, side not specified ☐ Right oophorectomy ☐ Left oophorectomy ☐ Bilateral salpingectomy ☐ Right salpingectomy ☐ Left salpingectomy ☐ Salpingectomy, side not specified ☐ Vaginal cuff resection ☐ Omentectomy ☐ Peritoneal biopsies ☐ Peritoneal washing ☐ Lymphadenectomy ☐ Core needle biopsy ☐ Fine needle aspirate ☐ Other Method (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 211a, otherwise, skip to Question 212.***
211a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
212	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
213	Metastatic/ recurrent site	☐ Endometrium ☐ Lower uterine segment ☐ Pelvic recurrence ☐ Soft tissue ☐ Right ovary ☐ Left ovary ☐ Right fallopian tube	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 213a, otherwise, skip to Question 214.***



Enrollment: Endometrium

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

		☐ Exta-abdominal lymph node(s) ☐ Peritoneum ☐ Lung ☐ Liver ☐ Adrenal gland ☐ Brain ☐ Bone ☐ Left fallopian tube ☐ Right tubo-ovarian ☐ Left tubo-ovarian ☐ Pelvic lymph node(s) ☐ Para-aortic lymph node(s) ☐ Other (specify)		
213a	Other metastatic/ recurrent site	_____	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
214	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
215	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
216	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
217	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
218	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
219	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
220	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
221	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
Additional Metastatic/Recurrent Tumor Prognostic/Predictive/Lifestyle Features for Additional Metastatic/Recurrent Tumor Prognosis or Responsiveness to Treatment (Note: Questions 157-204 may be repeated to capture clinical molecular characterization information for additional metastatic/recurrent biospecimens.)				
Metastatic/Recurrent Tumor Model Information				
222	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***



Enrollment: Endometrium

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
223	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
224	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
225	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
226	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Additional Metastatic/Recurrent Biospecimen Tumor Model Information (if applicable)				
227	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
228	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
229	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
230	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
231	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Other Biospecimen Information				
232	Are you submitting an OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an OTHER tissue sample (e.g. pre-malignant, non-malignant, or dysplastic tissue, etc.) was collected for HCMI for this case. ***Note: If yes, proceed to Question 233.***
233	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
234	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
235	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
236	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.



Enrollment: Endometrium

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
237	Other method of cancer sample procurement	☐ Endometrial biopsy ☐ Hysteroscopy ☐ Dilation and curettage (D&C) ☐ Fine needle aspirate ☐ Core needle biopsy ☐ Other Method (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 237a, otherwise, skip to Question 238.***
237a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
238	Tissue type	☐ Pre-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 238a, otherwise, skip to Question 239.***
238a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
239	Anatomic site of OTHER tissue	☐ Endometrium ☐ Lower uterine segment ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 239a, otherwise, skip to Question 240.***
239a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.
240	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
241	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Additional OTHER biospecimen Information (if applicable)				
242	Are you submitting an additional OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an additional OTHER tissue sample (pre-malignant, non-malignant, or dysplastic tissue, etc.) is being submitted for HCMI for this case. ***Note: If yes, proceed to Question 243, otherwise, skip to Question 253.***
243	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
244	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
245	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
246	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
247	Other method of cancer sample procurement	☐ Endometrial biopsy ☐ Hysteroscopy ☐ Dilation and curettage (D&C) ☐ Fine needle aspirate	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 247a, otherwise, skip to Question 248.***



Enrollment: Endometrium

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

		☐ Core needle biopsy ☐ Other Method (specify)		
247a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
248	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
249	Tissue type	☐ Pre-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 249a, otherwise, skip to Question 250.***
249a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
250	Anatomic site of OTHER tissue	☐ Endometrium ☐ Lower uterine segment ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 250a, otherwise, skip to Question 251.***
250a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.
251	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
252	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Other Tissue Model Information				
253	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
254	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
255	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
256	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
257	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.
Additional Other Tissue Model Information (if applicable)				
258	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***



Enrollment: Endometrium

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
259	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
260	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
261	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
262	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.



Enrollment: Esophageal

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Form Notes: An Enrollment Form should be completed for each HCMI case upon qualification notice from Leidos. All information provided on this form should include activity from the Date of Initial Pathologic Diagnosis to the most recent Date of Last Contact with the patient.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	☐ Initial pathologic diagnosis ☐ Sample procurement ☐ First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.
Patient Information				
4	Gender	☐ Male ☐ Female ☐ Unspecified	2200604	Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
5	Height	_____	649	Provide the patient's height, in centimeters.
6	Weight	_____	651	Provide the patient's weight, in kilograms.
7	Body mass index (BMI)	_____	2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
8	Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown ☐ Not reported	2192199	Provide the patient's race using the defined categories. **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 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. **Black or African American:** A person having origins in any of the black racial groups of Africa. **Native Hawaiian or other Pacific Islander:** A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island. **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
9	Ethnicity	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Not reported	2192217	Provide the patient's ethnicity using the defined categories. **Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. **Not Hispanic or Latino:** A person not meeting the definition of Hispanic or Latino.



Enrollment: Esophageal

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
10	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.
11	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. ***Note: If the patient's age is greater than 32,872 days (90 years), please enter 32,872.***
12	Year of birth	_____	2896954	Provide the year of the patient's birth. If the patient was born prior to 1928, insert the date 1928.
13	Family history of cancer	☐ Same ☐ Different ☐ None ☐ Unknown	5832923	Has a first-degree relative of the patient been diagnosed with a cancer of the same or a different type?
14	Smoking history	☐ Lifelong non-smoker (<100 cigarettes smoked in a lifetime) ☐ Current smoker (includes daily and non-daily smokers) ☐ Current reformed smoker (duration not specified) ☐ Current reformed smoker for >15 years ☐ Current reformed smoker for ≤15 years	2181650	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories.
15	Metastasis at diagnosis assessment status	☐ Metastatic ☐ Non-metastatic (confirmed) ☐ Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor. ***Note: If metastatic at diagnosis, proceed to Question 16, otherwise, skip to Question 17.***
16	Metastatic site(s) at diagnosis	☐ Bone ☐ Brain ☐ Liver ☐ Lung ☐ Other (specify)	3108271	Indicate the site(s) of metastasis at the time of diagnosis of the primary tumor. ***Note: If the anatomic site of tumor tissue is not listed, proceed to Question 16a, otherwise, skip to Question 17.***
16a	Specify metastatic site(s)	_____	3128033	If the site of metastasis is not included on the provided list, specify the site of metastasis.
Biospecimen Information				
17	Tissue sample type(s) collected for HCMI for this case	☐ Normal tissue ☐ Primary tumor ☐ Metastatic ☐ Recurrent ☐ Other tissue	2006911	Please select all the tissue sample types submitted for HCMI with this case.
18	Number of NORMAL tissues biospecimens collected for HCMI for this case	_____	6584256	Please provide the number of normal tissue specimens obtained for HCMI for this case. ***Note: This number is expected to be 1.***
19	Number of PRIMARY cancer tissue biospecimens collected for HCMI model development for this case	_____	6584257	Please provide the number of primary tumor specimens obtained for HCMI for this case. ***Note: A single primary tumor biospecimen obtained that is portioned for both sequencing and model generation counts as 1 single primary tumor specimen. This number is expected to be 1.***



Enrollment: Esophageal

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
20	Number of METASTATIC/RECURRENT cancer tissue biospecimens collected for HCMI model development for this case	_____	6584258	Please provide the number of metastatic and/or recurrent cancer biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
21	Number of OTHER tissue biospecimens collected for HCMI model development for this case	_____	6584259	Please provide the number of pre-malignant, non-malignant, or dysplastic tissue biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
22	Total number of tissue biospecimens collected for HCMI for this case	_____	6584271	Please provide the total number of tissue biospecimens collected for HCMI for this case. ***Note: This number should be the sum of the normal, primary tumor, metastatic/ recurrent tumor, and other biospecimen counts above.***
Normal Control Information				
23	Normal tissue biospecimen ordinal	_____	6584264	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
24	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
25	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
26	Type of normal control	☐ Whole blood ☐ Buccal cells ☐ Buffy coat ☐ Lymphocytes ☐ Extracted DNA from blood ☐ Extracted DNA from saliva ☐ Extracted DNA from buccal cells ☐ Extracted DNA from normal tissue ☐ FFPE non-neoplastic tissue ☐ Non-neoplastic tissue	3081936	Indicate the type of normal control submitted for this case.
27	Anatomic site of normal tissue	☐ Esophagus – proximal third ☐ Esophagus – middle third ☐ Esophagus – distal third ☐ Other (specify) ☐ Not applicable	4132152	If non-neoplastic tissue was submitted as the normal control, select the anatomic site of the normal tissue. ***Note: If the anatomic site of normal tissue is not listed, proceed to Question 27a, otherwise, skip to Question 28.***



Enrollment: Esophageal

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
27a	Other anatomic site of normal tissue	_____	3288189	If non-neoplastic tissue, adjacent tissue, or normal tissue from another anatomic site was submitted as the normal control, provide the anatomic site of the normal tissue.
28	Distance from tumor to normal control tissue (if not blood)	☐ Adjacent (< or = 2cm) ☐ Distal (>2cm) ☐ Unknown ☐ Not applicable	3088708	Indicate the distance from the site of normal tumor collection to the primary tumor. ***Note: If normal tissue was not submitted, select 'Not applicable'.***
29	Normal tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the normal tissue sample collected for molecular characterization.
Primary Tumor Biospecimen Information				
30	ICD-10 code for primary tumor	☐ C15.0 ☐ C15.1 ☐ C15.2 ☐ C15.3 ☐ C15.4 ☐ C15.5 ☐ C15.8 ☐ C15.9 ☐ Other (specify)	3226287	Provide the ICD-10 code for the primary tumor as used to generate the ID3 for this subject. ***Note: If the ICD-10 code is not listed, proceed to 30a, otherwise, skip to Question 31.***
30a	Other ICD-10 code for primary tumor	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.
31	Tumor Morphology	☐ 8020/3 ☐ 8051/3 ☐ 8070/3 ☐ 8074/3 ☐ 8083/3 ☐ 8140/3 ☐ 8200/3 ☐ 8430/3 ☐ 8560/3 ☐ Other (specify)	3226275	Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor. ***Note: If the ICD-O-3 histology code of the primary tumor is not listed, proceed to Question 31a, otherwise, skip to Question 32.***
31a	Specify other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.
32	Tissue or organ of origin	☐ Esophagus ☐ Other (specify)	3427536	Using the patient's pathology/laboratory report, select the primary site of the disease. ***Note: If the primary site of the disease is not listed, proceed to Question 32a, otherwise skip to Question 33.***
32a	Other tissue or organ of origin	_____	5946219	If the primary site of the disease is not included on the previous list, provide the primary site of the disease.
33	Histological Type	☐ Esophageal cancer ☐ Other (specify)	3081932	Select the surgical pathology text description of the histological tumor type. ***Note: If the histological tumor type is not listed, proceed to Question 33a, otherwise, skip to Question 34.***
33a	Other histological type	_____	3294805	If the traditional surgical pathology text description of the histological tumor type is not included on the previous list, please specify the histological type.
34	Histological subtype	☐ Esophagus adenocarcinoma (NOS) ☐ Esophagus squamous cell carcinoma ☐ Other (specify)	3081934	Using the patient's pathology/laboratory report, select the histological subtype of the primary tumor. ***Note: If the histological subtype is not listed, proceed to Question 34a, otherwise, skip to Question 35.***
34a	Other histological subtype	_____	3124492	If the histological subtype for the primary tumor is not included in the provided list, specify the histological subtype.



Enrollment: Esophageal

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
35	Prior malignancy (of the same cancer type)	☐ Yes ☐ No ☐ Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
36	Prior malignancy (other cancer type)	☐ Yes ☐ No ☐ Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.
37	AJCC cancer staging edition	☐ 1st ☐ 2nd ☐ 3rd ☐ 4th ☐ 5th ☐ 6th ☐ 7th ☐ 8th	2722309	Select the AJCC staging handbook edition used to stage the patient's primary tumor.
38	Clinical stage group	☐ Stage 0 ☐ Stage I ☐ Stage IA ☐ Stage IB ☐ Stage II ☐ Stage IIA ☐ Stage IIB ☐ Stage III ☐ Stage IIIA ☐ Stage IIIB ☐ Stage IIIC ☐ Stage IV ☐ Stage IVA ☐ Stage IVB	3440332	Using the patient's pathology/laboratory report, select the clinical stage group of the primary tumor as defined by the American Joint Committee on Cancer (AJCC).
39	AJCC pathologic spread: Primary tumor (pT)	☐ T0 ☐ Tis ☐ T1 ☐ T1a ☐ T1b ☐ T2 ☐ T3 ☐ T4 ☐ T4a ☐ T4b ☐ TX	3045435	Using the patient's pathology/laboratory report, select the code for the pathologic T (primary tumor) as defined by the American Joint Committee on Cancer (AJCC).
40	AJCC pathologic spread: Lymph nodes (pN)	☐ N0 ☐ N1 ☐ N2 ☐ N3 ☐ NX	3203106	Using the patient's pathology/laboratory report, select the code for the pathologic N (nodal) as defined by the American Joint Committee on Cancer (AJCC).
41	AJCC pathologic spread: Distant metastases (pM)	☐ M0 ☐ M1	3045439	Using the patient's pathology/laboratory report, select the code for the pathologic M (metastasis) as defined by the American Joint Committee on Cancer (AJCC).
42	Tumor stage (pathological)	☐ Stage 0 ☐ Stage IA ☐ Stage IB ☐ Stage IC ☐ Stage IIA ☐ Stage IIB ☐ Stage IIIA ☐ Stage IIIB ☐ Stage IIIC ☐ Stage IV ☐ Stage IVA ☐ Stage IVB	3065862	Using the patient's pathology/laboratory report, in conjunction with the patient's medical record, select the stage as defined by the American Joint Committee on Cancer (AJCC).
43	Tumor grade	☐ G1-Well differentiated ☐ G2-Moderately differentiated ☐ G3-Poorly differentiated ☐ GX-Unknown	2785839	Using the patient's pathology/laboratory report, select the grade of the primary tumor.
Prognostic/Predictive/Lifestyle Features for Primary Tumor Prognosis or Responsiveness to Treatment				
44	Does the tumor cross the gastric/esophageal junction (GEJ)?	☐ Yes ☐ No ☐ Unknown	3295807	Indicate whether the tumor is located across the gastroesophageal junction.
45	Alcohol exposure intensity	☐ Lifelong non-drinker ☐ Non-drinker ☐ Occasional drinker ☐ Drinker ☐ Heavy drinker ☐ Not evaluated	3457767	Describe the patient's current level of alcohol use as self-reported by the patient.
46	Frequency of alcohol consumption (days per week)	_____	3114013	Describe the average number of days each week that the patient consumes an alcoholic beverage.



Enrollment: Esophageal

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
47	Did the patient have a prior clinical diagnosis of reflux disease?	☐ Yes ☐ No ☐ Unknown	3203079	Indicate whether the patient has a history of reflux disease. ***Note: If the patient was not diagnosed with reflux disease, skip to Question 49.***
48	How was the patient treated for reflux disease?	☐ Antacids ☐ H2 blockers ☐ Medically treated ☐ Proton pump inhibitors ☐ Surgically treated ☐ No treatment ☐ Unknown	3440206	If the patient was clinically diagnosed with reflux disease, select all methods by which the patient was treated.
49	Previous or current H. pylori infection?	☐ Previous ☐ Current ☐ Never ☐ Unknown	3440211	Indicate whether the patient was previously or is currently diagnosed with Helicobacter pylori infection.
50	Previous or current diagnosis of Barrett's Esophagus?	☐ Yes ☐ No ☐ Unknown	3203140	Indicate whether the patient had a previous or has a current diagnosis of Barrett's esophagus. ***Note: If the patient was not diagnosed with Barrett's Esophagus, skip to Question 52.***
51	Were goblet cells present?	☐ Yes ☐ No ☐ Unknown	3440216	If the patient was clinically diagnosed with Barrett's Esophagus, indicate whether there were goblet cells present.
52	Esophageal columnar metaplasia present?	☐ Yes ☐ No ☐ Unknown	3440218	Indicate whether the patient had esophageal columnar metaplasia present.
53	Goblet cells of esophageal columnar mucosa present (i.e. possible specialized Barrett's esophagus mucosa)?	☐ Yes ☐ No ☐ Unknown	3440219	Indicate whether goblet cells were present in esophageal columnar mucosa.
54	Degree of dysplasia within the non-cancerous esophageal columnar mucosa	☐ Negative/no dysplasia ☐ Low grade dysplasia ☐ High grade dysplasia ☐ Indefinite for dysplasia ☐ Unknown	3440917	Provide the patient's degree of dysplasia within the non-cancerous esophageal columnar mucosa.
55	Number of pack years smoked	_____	2955385	Provide the number of pack years the patient smoked. ***Note: This is calculated using the number of cigarettes smoked per day times the number of years smoked, divided by 20. For example, if a patient smoked 5 cigarettes per day times 10 years, divided by 20, the patient would have 2.5 pack years (e.g. 5 x 10 / 20 = 2.5).***
56	Tobacco smoking quit year	_____	2228610	Provide the year the patient quit smoking. ***Note: If the patient has not quit smoking, never smoked, or the year is unknown, leave the response section blank.***
Primary Tumor Sample Information				
57	Are you submitting a primary tumor tissue sample for this case?	☐ Yes ☐ No		***If yes, proceed to question 58.*** ***If submitting a metastatic/recurrent tumor sample, proceed to Question 84.***
58	Primary tumor biospecimen ordinal	_____	6584265	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number should be "1".***



Enrollment: Esophageal

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
59	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
60	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
61	Sample represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this primary tumor specimen represent the PRIMARY DIAGNOSIS for this Case ID3? ***Note: If no, continue to Question 62, otherwise, skip to Question 63.***
62	Specify the ICD-10 code	_____	3226287	Provide the ICD-10 code for the primary tumor used to generate the model submitted to HCMI.
63	Tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the tumor tissue sample collected for molecular characterization.
64	Anatomic Site of tumor from which Model was Derived	☐ Esophagus – proximal third ☐ Esophagus – middle third ☐ Esophagus – distal third ☐ Gastroesophageal junction ☐ Bone ☐ Brain ☐ Liver ☐ Lung ☐ Lymph node ☐ Other (specify)	4214629	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI. ***Note: If the tissue or organ of origin is not listed, proceed to Question 64a. Otherwise, skip to Question 65.***
64a	Other anatomic site from which the tumor was obtained	_____	5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.
65	Method of cancer sample procurement	☐ Endoscopic biopsy ☐ Endoscopic mucosal resection ☐ Surgical resection ☐ Laparoscopic biopsy ☐ Other (specify)	3103514	Provide the procedure performed to obtain the primary tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 65a, otherwise, skip to Question 66.***
65a	Specify the other method of tumor sample procurement	_____	2006730	Specify the procedure performed to obtain the primary tumor tissue, if not included in the previous list.
66	Number of days from index date to date of tumor sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the tumor tissue submitted for HCMI.
67	Tumor tissue type	☐ Primary ☐ Additional Primary ☐ NOS	3288124	Provide the primary tumor tissue type for this sample.
Primary Tumor Model Information				
68	Primary model biospecimen ordinal	_____	6594596	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number is expected to be "1".***
69	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.



Enrollment: Esophageal

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
70	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
71	Model represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this MODEL represent the PRIMARY DIAGNOSIS for this Case ID3?
72	Model's primary tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the PRIMARY TUMOR TISSUE from which this model is derived.
73	Model's primary tumor biospecimen ordinal	_____	6584265	Enter the biospecimen ordinal of the PRIMARY TUMOR TISSUE from which this model is derived.
Treatment Information				
74	History of neoadjuvant treatment	☐ No ☐ Yes; radiation prior to resection ☐ Yes; pharmaceutical treatment prior to resection ☐ Yes; both radiation and pharmaceutical treatment prior to resection ☐ Unknown	3382737	Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment. ***Note: Pharmaceutical therapy is addressed in Questions 75-81. Radiation therapy is addressed in Questions 82-83.***
75	Neoadjuvant chemotherapy type	☐ Cytotoxic chemotherapy ☐ Hormonal ☐ Immunotherapy (cellular and immune checkpoint) ☐ Targeted therapy (small molecule inhibitors and targeted antibodies) ☐ Not applicable	5832928	Select all neoadjuvant chemotherapy types that were administered to the patient. ***Note: Cytotoxic chemotherapy is addressed in Questions 76-77. Immunotherapy is addressed in Questions 78-79. Targeted therapy is addressed in Questions 80-81.***
76	Neoadjuvant chemotherapeutic regimen	☐ Cisplatin; 5-fluorouracil (CF) ☐ Cisplatin; Capecitabine (CX) ☐ Epirubicin; Cisplatin; 5-fluorouracil (ECF) ☐ Epirubicin; Cisplatin; Capecitabine (ECX) ☐ Epirubicin; Oxaliplatin; Capecitabine (EOX) ☐ Other (specify) ☐ Chemotherapy not given	2853313	Select all chemotherapeutics used for neoadjuvant therapy. ***Note: If neoadjuvant chemotherapy was not given, skip to Question 78. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 76a, otherwise, skip to Question 77.***
76a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapies administered.
77	Days to neoadjuvant chemotherapy treatment from index date	_____	5102411	Provide the number of days from index date to the date of treatment with neoadjuvant chemotherapy.
78	Immunotherapy	_____	2185614	Specify the name of the immunotherapy administered. ***Note: If immunotherapy was not given, skip to Question 80, otherwise proceed to Question 79.***
79	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
80	Targeted Therapy	☐ Ramucirumab ☐ Trastuzumab ☐ Other (specify)	5880217	Select the targeted therapy administered to the patient. ***Note: If the targeted therapy regimen is not listed, proceed to Question 80a, otherwise, skip to Question 81.***
80a	Specify targeted therapy	_____	4308476	Provide the name of the targeted therapy administered to the patient.



Enrollment: Esophageal

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
81	Days to targeted therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with targeted therapy.
82	Radiation therapy administered type	☐ 2D conventional ☐ 3D conformal ☐ Brachytherapy HDR ☐ Brachytherapy LDR ☐ IMRT ☐ Proton Beam ☐ Stereotactic Body RT ☐ Stereotactic Radiosurgery ☐ WBRT ☐ Other (specify) ☐ Unspecified ☐ Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. ***Note: If radiation therapy was not administered, proceed to Question 84. If the radiation therapy is not listed, proceed to Question 82a, otherwise, skip to Question 83.***
82a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
83	Days to radiation treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with radiation therapy.
Metastatic/Recurrent Tumor Biospecimen Information				
84	Are you submitting a metastatic/recurrent tumor tissue sample?	☐ Yes ☐ No		Indicate whether a metastatic/recurrent tumor biospecimen was collected for this ID3 case. ***Note: If yes, proceed to Question 85. If submitting an OTHER tissue sample, proceed to Question 136.***
85	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1", the second should be number "2", etc.***
86	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
87	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
88	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
89	Number of days from index date to date of diagnosis of metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic/recurrent disease.
90	Method of metastatic/ recurrent cancer sample procurement	☐ Endoscopic biopsy ☐ Endoscopic mucosal resection ☐ Surgical resection ☐ Laparoscopic biopsy ☐ Other (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 90a, otherwise, skip to Question 91.***
90a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
91	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.



Enrollment: Esophageal

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
92	Metastatic/recurrent site	☐ Esophagus - proximal third ☐ Esophagus - middle third ☐ Esophagus - distal third ☐ Gastroesophageal junction ☐ Bone ☐ Brain ☐ Liver ☐ Lung ☐ Lymph node ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 92a, otherwise, skip to Question 93.***
92a	Other metastatic/ recurrent site	_____	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
93	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
94	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
95	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
96	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
97	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
98	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
99	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
100	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
Prognostic/Predictive/Lifestyle Features for Metastatic/Recurrent Tumor Prognosis or Responsiveness to Treatment				
101	Does the tumor cross the gastric/esophageal junction (GEJ)?	☐ Yes ☐ No ☐ Unknown	3295807	Indicate whether the tumor is located across the gastroesophageal junction.
102	Esophageal columnar metaplasia present?	☐ Yes ☐ No ☐ Unknown	3440218	Indicate whether the patient had esophageal columnar metaplasia present.



Enrollment: Esophageal

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
103	Goblet cells of esophageal columnar mucosa present (i.e. possible specialized Barrett's esophagus mucosa)?	☐ Yes ☐ No ☐ Unknown	3440219	Indicate whether goblet cells were present in esophageal columnar mucosa.
104	Degree of dysplasia within the non-cancerous esophageal columnar mucosa	☐ Negative/no dysplasia ☐ Low grade dysplasia ☐ High grade dysplasia ☐ Indefinite for dysplasia ☐ Unknown	3440917	Provide the patient's degree of dysplasia within the non-cancerous esophageal columnar mucosa.
Additional Metastatic/Recurrent Tumor Biospecimen Information (if applicable)				
105	Are you submitting an additional metastatic/ recurrent tumor tissue sample?	☐ Yes ☐ No		A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen. ***Note: If yes, proceed to Question 106, otherwise, skip to Question 126.***
106	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. The first biospecimen should be number "1," the second should be number "2," etc.
107	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
108	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
109	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
110	Number of days from index date to date of diagnosis of additional metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of additional metastatic/recurrent disease.
111	Method of metastatic/ recurrent cancer sample procurement	☐ Endoscopic biopsy ☐ Endoscopic mucosal resection ☐ Surgical resection ☐ Laparoscopic biopsy ☐ Other (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 111a, otherwise, skip to Question 112.***
111a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
112	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.



Enrollment: Esophageal

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
113	Metastatic/ recurrent site	☐ Esophagus - proximal third ☐ Esophagus - middle third ☐ Esophagus - distal third ☐ Gastroesophageal junction ☐ Bone ☐ Brain ☐ Liver ☐ Lung ☐ Lymph node ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 113a, otherwise, skip to Question 114.***
113a	Other metastatic/ recurrent site	_____	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
114	Site of relapse	☐ Local ☐ Distant ☐ Regional ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
115	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
116	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
117	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
118	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
119	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
120	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
121	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
Prognostic/Predictive/Lifestyle Features for Additional Metastatic/Recurrent Tumor Prognosis or Responsiveness to Treatment				
122	Does the tumor cross the gastric/esophageal junction (GEJ)?	☐ Yes ☐ No ☐ Unknown	3295807	Indicate whether the tumor is located across the gastroesophageal junction.
123	Esophageal columnar metaplasia present?	☐ Yes ☐ No ☐ Unknown	3440218	Indicate whether the patient had esophageal columnar metaplasia present.
124	Goblet cells of esophageal columnar mucosa present (i.e. possible specialized Barrett's esophagus mucosa)?	☐ Yes ☐ No ☐ Unknown	3440219	Indicate whether goblet cells were present in esophageal columnar mucosa.



Enrollment: Esophageal

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
125	Degree of dysplasia within the non-cancerous esophageal columnar mucosa	☐ Negative/no dysplasia ☐ Low grade dysplasia ☐ High grade dysplasia ☐ Indefinite for dysplasia ☐ Unknown	3440917	Provide the patient's degree of dysplasia within the non-cancerous esophageal columnar mucosa.
Metastatic/Recurrent Tumor Model Information				
126	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
127	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
128	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
129	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
130	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Additional Metastatic/Recurrent Biospecimen Tumor Model Information (if applicable)				
131	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
132	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
133	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
134	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
135	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Other Biospecimen Information				
136	Are you submitting an OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an OTHER tissue sample (e.g. pre-malignant, non-malignant, or dysplastic tissue, etc.) was collected for HCMI for this case. ***Note: If yes, proceed to Question 137.***
137	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***



Enrollment: Esophageal

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
138	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
139	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
140	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
141	Other method of cancer sample procurement	☐ Endoscopic biopsy ☐ Endoscopic mucosal resection ☐ Surgical resection ☐ Laparoscopic biopsy ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 141a, otherwise, skip to Question 142.***
141a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
142	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
143	Tissue type	☐ Non-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 143a, otherwise, skip to Question 144.***
143a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
144	Anatomic site of OTHER tissue	☐ Esophagus - proximal third ☐ Esophagus - middle third ☐ Esophagus - distal third ☐ Gastroesophageal junction ☐ Bone ☐ Brain ☐ Liver ☐ Lung ☐ Lymph node ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 144a, otherwise, skip to Question 145.***
144a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.
145	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
146	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Additional OTHER biospecimen Information (if applicable)				
147	Are you submitting an additional OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an additional OTHER tissue sample (pre-malignant, non-malignant, or dysplastic tissue, etc.) is being submitted for HCMI for this case. ***Note: If yes, proceed to Question 148, otherwise, skip to Question 158.***
148	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***



Enrollment: Esophageal

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
149	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
150	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
151	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
152	Other method of cancer sample procurement	☐ Endoscopic biopsy ☐ Endoscopic mucosal resection ☐ Surgical resection ☐ Laparoscopic biopsy ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 152a, otherwise, skip to Question 153.***
152a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
153	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
154	Tissue type	☐ Non-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 154a, otherwise, skip to Question 155.***
154a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
155	Anatomic site of OTHER tissue	☐ Esophagus - proximal third ☐ Esophagus - middle third ☐ Esophagus - distal third ☐ Gastroesophageal junction ☐ Bone ☐ Brain ☐ Liver ☐ Lung ☐ Lymph node ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 155a, otherwise, skip to Question 156.***
155a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.
156	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
157	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Other Tissue Model Information				
158	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***



Enrollment: Esophageal

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
159	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
160	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
161	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
162	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.
Additional Other Tissue Model Information (if applicable)				
163	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
164	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
165	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
166	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
167	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.



Enrollment: Ewing Sarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Form Notes: An Enrollment Form should be completed for each HCMI case upon qualification notice from Leidos. All information provided on this form should include activity from the Date of Initial Pathologic Diagnosis to the most recent Date of Last Contact with the patient.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	☐ Initial pathologic diagnosis ☐ Sample procurement ☐ First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.
Normal Control Information				
4	Type of normal control	☐ Whole blood ☐ Buccal cells ☐ Buffy coat ☐ Lymphocytes ☐ Extracted DNA from blood ☐ Extracted DNA from saliva ☐ Extracted DNA from buccal cells ☐ Extracted DNA from normal tissue ☐ FFPE non-neoplastic tissue ☐ Non-neoplastic tissue	3081936	Indicate the type of normal control submitted for this case.
Tumor Tissue Collected for Molecular Characterization, Sample Information				
5	Tumor tissue sample preservation method	☐ FFPE ☐ Fresh ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the tumor tissue sample collected to be used for molecular characterization.
Cancer Model Information				
6	Anatomic site of tumor from which model was derived	☐ Ascites ☐ Bone ☐ Bone marrow ☐ Chest wall ☐ Lower extremity ☐ Lung ☐ Lymph node ☐ Pelvis ☐ Soft tissue ☐ Spine ☐ Upper extremity ☐ Other (specify)	4214629	Indicate the anatomic site of the tumor tissue used to generate the model for the HCMI. ***Note: If the anatomic site of tumor tissue is not listed, proceed to Question 6a, otherwise, skip to Question 7.***
6a	Other anatomic site	_____	5946219	If the anatomic site for the tumor submitted to HCMI is not included on the provided list, specify the anatomic site.
7	Method of cancer sample procurement	☐ Core needle biopsy ☐ Excisional biopsy ☐ Fine needle aspiration ☐ Incisional biopsy ☐ Tumor resection ☐ Other (specify)	3103514	Indicate the procedure performed to obtain the tumor tissue used to generate the model for HCMI. ***Note: If the method of sample procurement is not listed, proceed to Question 7a, otherwise, skip to Question 8.***
7a	Other method of sample procurement	_____	2006730	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.



Enrollment: Ewing Sarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
8	Number of days from index date to date of cancer sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the tumor tissue submitted for HCMI.
9	ICD-10 code for model tumor	☐ C40.0 ☐ C41.2 ☐ C40.1 ☐ C41.4 ☐ C40.2 ☐ C41.8 ☐ C40.3 ☐ C41.9 ☐ C40.8 ☐ C77.9 ☐ C40.9 ☐ C78.0 ☐ C41.0 ☐ C79.5 ☐ C41.1 ☐ Other (specify)	3226287	Provide the ICD-10 code for the tumor used to generate the model submitted to HCMI. ***Note: If the ICD-10 code is not listed, proceed to Question 9a, otherwise, skip to Question 10.***
9a	Other ICD-10 code	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.
10	Tumor tissue type	☐ Premalignant ☐ Primary ☐ Recurrent ☐ Metastatic ☐ Additional primary ☐ NOS	3288124	Provide the tumor tissue type for the biospecimen used to produce the model for the HCMI. ***Note: If 'Metastatic' is selected, continue to answer through Question 18. If the tissue is not 'Metastatic', skip to Question 19.***
Metastatic Model Information *(only complete Questions 13-20 if 'Metastatic' was selected in Question 12)*				
11	Age at diagnosis of metastasis	_____	6032752	Provide the age (in days) of the patient when diagnosed with metastatic disease. If the patient's age is greater than 32,507 days (89 years), please enter 32,507.
12	Number of days from index date to date of diagnosis of metastasis	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic disease.
13	Metastatic site	☐ Lung ☐ Bone ☐ Bone marrow ☐ Lymph node(s) ☐ Lymph node(s)- distant ☐ Other (specify)	6119068	Select the site from which the metastatic tissue used to develop the model was derived. ***Note: If the metastatic site is not listed, proceed to Question 13a, otherwise, skip to Question 14.***
13a	Other metastatic site	_____	3128033	If not included in the previous list, specify the site from which the metastatic tissue used to develop the model was derived.
14	Maintenance and/or consolidation therapy administered prior to collection of metastatic tissue	_____	6119066	If applicable, provide the name of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic tissue used to develop the model. ***Note: If maintenance and/or consolidation therapy was not administered, skip to Question 19.***
15	Days from index date to start of maintenance and/or consolidation therapy	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.



Enrollment: Ewing Sarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
16	Days from index date to last known date of maintenance and/or consolidation therapy treatment	_____	65167	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
17	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing treatment.
18	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
Patient Information				
19	Gender	☐ Male ☐ Female ☐ Unspecified	2200604	Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
20	Height	_____	649	Provide the patient's height, in centimeters.
21	Weight	_____	651	Provide the patient's weight, in kilograms.
22	Body mass index (BMI)	_____	2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
23	Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown ☐ Not allowed to collect	2192199	Provide the patient's race using the defined categories. **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 peoples of the Far East, Southeast Asia, or in the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Phillippine Islands, Thailand, and Vietnam. **Black or African American:** A person having origins in any of the black racial groups of Africa. **Native Hawaiian or other Pacific Islander:** A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island. **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
24	Ethnicity	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Not allowed to collect	2192217	Provide the patient's ethnicity using the defined categories. **Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. **Not Hispanic or Latino:** A person not meeting the definition of Hispanic or Latino.
25	Year of birth	_____	2896954	Provide the year of the patient's birth. If the patient was born prior to 1928, insert the date 1928.
26	Family history of cancer	☐ Same ☐ Different ☐ None ☐ Unknown	5832923	Has a first-degree relative of the patient been diagnosed with a cancer of the same or a different type?



Enrollment: Ewing Sarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
27	Tobacco smoking history	☐ Lifelong non-smoker (<100 cigarettes smoked in a lifetime) ☐ Current smoker (includes daily and non-daily smokers) ☐ Current reformed smoker (duration not specified) ☐ Current reformed smoker for >15 years ☐ Current reformed smoker for ≤15 years	2181650	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories.
Primary Tumor Diagnosis Information				
28	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.
29	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. If the patient's age is greater than 32,507 days (89 years), please enter 32,507.
30	Morphology	☐ 9260/3 ☐ Other (specify)	3226275	Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor. ***Note: If the morphology is not listed, proceed to Question 30a, otherwise, skip to Question 31.***
30a	Other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.
31	Tissue or organ of origin	☐ Chest wall ☐ Limb ☐ Pelvis ☐ Soft tissue ☐ Spine ☐ Other (specify)	3427536	Using the patient's pathology/laboratory report, select the primary site of the disease. ***Note: If the tissue or organ of origin is not listed, proceed to Question 31a, otherwise, skip to Question 32.***



Enrollment: Ewing Sarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
31a	Other tissue or organ of origin	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	3427536	If the primary site of the disease is not included on the previous list, select the primary site of the disease.
32	Histological type	☐ Malignant bone neoplasm ☐ Other (specify)	3081932	Provide the traditional surgical pathology text description of the histological tumor type. ***Note: If the histological type is not listed, proceed to Question 32a, otherwise, skip to Question 33.***
32a	Other histological type	_____	3294805	If the traditional surgical pathology text description of the histological tumor type is not included on the previous list, please specify the histological type.
33	Prior malignancy (of the same cancer type)	☐ Yes ☐ No ☐ Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
34	Prior malignancy (other cancer type)	☐ Yes ☐ No ☐ Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.
35	Tumor stage	☐ Localized ☐ Regional spread ☐ Distant ☐ Unknown	4927914	Provide the stage of the patient's Ewing sarcoma tumor.
36	Metastasis at diagnosis assessment status	☐ Metastatic ☐ Non-metastatic (confirmed) ☐ Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor.



Enrollment: Ewing Sarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
37	Metastatic site(s) at diagnosis	☐ Lung ☐ Bone ☐ Bone marrow ☐ Lymph node(s) ☐ Lymph node(s)- distant ☐ Other (specify)	3029815	Indicate all the site(s) of metastasis at the time of diagnosis of the primary tumor. ***Note: If the metastatic site(s) is not listed, proceed to Question 37a, otherwise, skip to Question 38.***
37a	Specify metastatic site(s)	_____	3128033	If the site(s) of metastasis at the time of diagnosis of the primary tumor is not included in the provided list, specify the site(s).
38	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, select all sites of relapse. ***Note: If the primary tumor did not relapse, select 'Not applicable'.***
39	Primary tumor size (cm; largest dimension)	_____	1140	Provide the largest dimension of the primary tumor, in centimeters.
Prognostic/Predictive/Lifestyle Features for Tumor Prognosis or Responsiveness to Treatment				
40	Percent tumor necrosis (at resection, primary tumor)	_____	2841237	Provide the percent necrosis of the primary tumor at the time of resection.
41	Was CD99 IHC performed?	☐ Yes ☐ No ☐ Unknown	6061817	Indicate whether analysis of CD99 expression was performed by immunohistochemistry (IHC). ***Note: If CD99 IHC was not performed, skip to Question 43.***
42	CD99 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063675	Indicate the results of IHC analysis for CD99 expression.
43	Was Ewing Sarcoma translocation analysis performed?	☐ Yes ☐ No ☐ Unknown	6062599	Indicate whether a translocation analysis for Ewing sarcoma was performed. ***Note: If Ewing Sarcoma translocation analysis was not performed, skip to Question 46.***
44	Was a Ewing Sarcoma translocation identified?	☐ Yes ☐ No	6063522	Indicate whether a chromosomal translocation related to Ewing sarcoma was identified. ***Note: If a chromosomal translocation was not identified, skip to Question 46.***
45	If translocation identified in Ewing Sarcoma, which one?	☐ BCOR-CCNB3 ☐ CIC-DUX4 ☐ EWSR1-ATF1 ☐ EWSR1-CREB1 ☐ EWSR1-ETV1 ☐ EWSR1-ETV4 ☐ EWSR1-FLI1 ☐ EWSR1-PBX1 ☐ EWSR1-POU5F1 ☐ EWSR1-ZNF444 ☐ FUS-CREB3L2 ☐ Other translocation (specify) ☐ Unknown	4927975	Select the translocation identified in Ewing sarcoma. ***Note: If the Ewing Sarcoma translocation is not listed, proceed to Question 45a, otherwise, skip to Question 46.***
45a	Specify other translocation identified	_____	4927991	If the translocation was not provided in the previous list, please specify the translocation identified.



Enrollment: Ewing Sarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Treatment Information				
46	History of neoadjuvant treatment	☐ No ☐ Yes; radiation prior to resection ☐ Yes; pharmaceutical treatment prior to resection ☐ Yes; both radiation and pharmaceutical treatment prior to resection ☐ Unknown	3382737	Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment. ***Note: Radiation therapy is addressed in Questions 54-55. Pharmaceutical therapy is addressed in Questions 47-53.***
47	Neoadjuvant chemotherapy type	☐ Cytotoxic chemotherapy ☐ Hormonal ☐ Immunotherapy (cellular and immune checkpoint) ☐ Targeted therapy (small molecule inhibitors and targeted antibodies) ☐ Not applicable	5832928	Select all neoadjuvant chemotherapy types that were administered to the patient. ***Note: Cytotoxic chemotherapy is addressed in Questions 48-49. Immunotherapy is addressed in Questions 50-51. Targeted therapy is addressed in Questions 52-53.***
48	Neoadjuvant chemotherapeutic regimen	☐ Cyclophosphamide ☐ Doxorubicin ☐ Etoposide ☐ Ifosfamide ☐ Vincristine ☐ Vincristine, actinomycin-D, cyclophosphamide (VAC) ☐ Vincristine, doxorubicin, cyclophosphamide, ifosfamide, etoposide (VDC/IE) ☐ Vincristine, actinomycin-D, cyclophosphamide, vincristine, irinotecan (VAC/VI) ☐ Ifosfamide, carboplatin, etoposide (ICE) ☐ Vincristine, irinotecan, temozolomide (VIT) ☐ High-dose methotrexate, doxorubicin, cisplatin (MAP) ☐ Other (specify) ☐ Chemotherapy not given	2853313	Select all chemotherapeutics used for neoadjuvant therapy. ***Note: If neoadjuvant chemotherapy was not given, skip to Question 50. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 48a, otherwise, skip to Question 49.***
48a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapy.
49	Days to neoadjuvant chemotherapy treatment from index date	_____	5102411	Provide the number of days from index date to the date of treatment with neoadjuvant chemotherapy.
50	Immunotherapy name, specify	_____	2185614	Specify the name of the immunotherapy administered.
51	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
52	Targeted therapy	☐ IGF-1R inhibitor ☐ Other (specify)	6078893	Select the targeted therapy administered to the patient. ***Note: If targeted therapy was not administered, skip to Question 53. If the targeted therapy is not listed, proceed to Question 52a, otherwise, skip to Question 53.***
52a	Other targeted therapy	_____	4308476	If the targeted therapy is not included in the provided list, specify targeted therapy.



Enrollment: Ewing Sarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
53	Days to targeted therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with targeted therapy.
54	Radiation therapy administered type	☐ 2D conventional ☐ 3D conformal ☐ Brachytherapy HDR ☐ Brachytherapy LDR ☐ IMRT ☐ Proton Beam ☐ Stereotactic Body RT ☐ Stereotactic Radiosurgery ☐ WBRT ☐ Other (specify) ☐ Unspecified ☐ Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. ***Note: If radiation therapy was not administered, skip the remaining questions. If the radiation therapy is not listed, proceed to Question 54a, otherwise, skip to Question 55.***
54a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
55	Days to radiation treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with radiation therapy.



Enrollment: Glioblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Form Notes: An Enrollment Form should be completed for each HCMI case upon qualification notice from Leidos. All information provided on this form should include activity from the Date of Initial Pathologic Diagnosis to the most recent Date of Last Contact with the patient.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	☐ Initial pathologic diagnosis ☐ Sample procurement ☐ First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.
Patient Information				
4	Gender	☐ Male ☐ Female ☐ Unspecified	2200604	Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
5	Height	_____	649	Provide the patient's height, in centimeters.
6	Weight	_____	651	Provide the patient's weight, in kilograms.
7	Body mass index (BMI)	_____	2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
8	Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown ☐ Not reported	2192199	Provide the patient's race using the defined categories. **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 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. **Black or African American:** A person having origins in any of the black racial groups of Africa. **Native Hawaiian or other Pacific Islander:** A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island. **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
9	Ethnicity	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Not reported	2192217	Provide the patient's ethnicity using the defined categories. **Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. **Not Hispanic or Latino:** A person not meeting the definition of Hispanic or Latino.



Enrollment: Glioblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
10	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.
11	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. ***Note: If the patient's age is greater than 32,872 days (90 years), please enter 32,872.***
12	Year of birth	_____	2896954	Provide the year of the patient's birth. If the patient was born prior to 1928, insert the date 1928.
13	Family history of cancer	☐ Same ☐ Different ☐ None ☐ Unknown	5832923	Has a first-degree relative of the patient been diagnosed with a cancer of the same or a different type?
14	Smoking history	☐ Lifelong non-smoker (<100 cigarettes smoked in a lifetime) ☐ Current smoker (includes daily and non-daily smokers) ☐ Current reformed smoker (duration not specified) ☐ Current reformed smoker for >15 years ☐ Current reformed smoker for ≤15 years	2181650	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories.
15	Metastasis at diagnosis assessment status	☐ Metastatic ☐ Non-metastatic (confirmed) ☐ Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor.
16	Hereditary cancer predisposition syndrome	☐ Fanconi anemia ☐ Gorlin syndrome ☐ Li-Fraumeni syndrome ☐ Lynch syndrome ☐ Rubinstein-Taybi syndrome ☐ Turcot syndrome ☐ Unknown ☐ Not applicable	6002201	Indicate all hereditary cancer predisposition syndromes identified in the patient.
Biospecimen Information				
17	Tissue sample type(s) collected for HCMI for this case	☐ Normal tissue ☐ Primary tumor ☐ Metastatic ☐ Recurrent ☐ Other tissue	2006911	Please select all the tissue sample types submitted for HCMI with this case.
18	Number of NORMAL tissues biospecimens collected for HCMI for this case	_____	6584256	Please provide the number of normal tissue specimens obtained for HCMI for this case. ***Note: This number is expected to be 1.***
19	Number of PRIMARY cancer tissue biospecimens collected for HCMI model development for this case	_____	6584257	Please provide the number of primary tumor specimens obtained for HCMI for this case. ***Note: A single primary tumor biospecimen obtained that is portioned for both sequencing and model generation counts as 1 single primary tumor specimen. This number is expected to be 1.***
20	Number of METASTATIC/RECURRENT cancer tissue biospecimens collected for HCMI model development for this case	_____	6584258	Please provide the number of metastatic and/or recurrent cancer biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***



Enrollment: Glioblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
21	Number of OTHER tissue biospecimens collected for HCMI model development for this case	_____	6584259	Please provide the number of pre-malignant, non-malignant, or dysplastic tissue biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
22	Total number of tissue biospecimens collected for HCMI for this case	_____	6584271	Please provide the total number of tissue biospecimens collected for HCMI for this case. ***Note: This number should be the sum of the normal, primary tumor, metastatic/ recurrent tumor, and other biospecimen counts above.***
Normal Control Information				
23	Normal tissue biospecimen ordinal	_____	6584264	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
24	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
25	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
26	Type of normal control	☐ Whole blood ☐ Buccal cells ☐ Buffy coat ☐ Lymphocytes ☐ Extracted DNA from blood ☐ Extracted DNA from saliva ☐ Extracted DNA from buccal cells ☐ Extracted DNA from normal tissue ☐ FFPE non-neoplastic tissue ☐ Non-neoplastic tissue	3081936	Indicate the type of normal control submitted for this case.
27	Specify anatomic site of normal tissue	_____	3288189	If non-neoplastic tissue, adjacent tissue, or normal tissue from another anatomic site was submitted as the normal control, provide the anatomic site of the normal tissue.
28	Distance from tumor to normal control tissue (if not blood)	☐ Adjacent (< or = 2cm) ☐ Distal (>2cm) ☐ Unknown ☐ Not applicable	3088708	Indicate the distance from the site of normal tumor collection to the primary tumor. ***Note: If normal tissue was not submitted, select 'Not applicable'.***
29	Normal tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the normal tissue sample collected for molecular characterization.



Enrollment: Glioblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Primary Tumor Biospecimen Information				
30	ICD-10 code for primary tumor	☐ C71.0 ☐ C71.1 ☐ C71.2 ☐ C71.3 ☐ C71.4 ☐ C71.5 ☐ C71.9 ☐ C72.9 ☐ Other (specify)	3226287	Provide the ICD-10 code for the primary tumor as used to generate the ID3 for this subject. ***Note: If the ICD-10 code is not listed, proceed to 30a, otherwise, skip to Question 31.***
30a	Other ICD-10 code for primary tumor	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.
31	Tumor Morphology	☐ 9440/3 ☐ 9441/3 ☐ 9442/3 ☐ Other (specify)	3226275	Using the patient's pathology/ laboratory report, provide the ICD-O-3 histology code of the primary tumor. ***Note: If the ICD-O-3 histology code of the primary tumor is not listed, proceed to Question 31a, otherwise, skip to Question 32.***
31a	Specify other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.
32	Tissue or organ of origin	☐ Brain ☐ Other (specify)	3427536	Using the patient's pathology/ laboratory report, select the primary site of the disease. ***Note: If the primary site of the disease is not listed, proceed to Question 32a, otherwise skip to Question 33***
32a	Other tissue or organ of origin	_____	5946219	If the primary site of the disease is not included on the previous list, provide the primary site of the disease.
33	Histological Type	☐ Glioblastoma ☐ Other (specify)	3081932	Select the surgical pathology text description of the histological tumor type. ***Note: If the histological tumor type is not listed, proceed to Question 33a, otherwise, skip to Question 34.***
33a	Other histological type	_____	3294805	If the traditional surgical pathology text description of the histological tumor type is not included on the previous list, please specify the histological type.
34	Histological subtype	☐ Giant cell glioblastoma ☐ Gliosarcoma ☐ NOS ☐ Other (specify)	3081934	Using the patient's pathology/ laboratory report, select the histological subtype of the primary tumor. ***Note: If the histological subtype is not listed, proceed to Question 34a, otherwise, skip to Question 35.***
34a	Other histological subtype	_____	5946219	If the histological subtype for the primary tumor is not included in the provided list, specify the histological subtype.
35	Prior malignancy (of the same cancer type)	☐ Yes ☐ No ☐ Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
36	Prior malignancy (other cancer type)	☐ Yes ☐ No ☐ Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.
37	WHO histologic grade	☐ Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Grade 4 ☐ Unknown	2181858	Provide the WHO histologic grade of the primary tumor.



Enrollment: Glioblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
38	Is necrosis present?	☐ Yes ☐ No ☐ Unknown	64740	Indicate if there is evidence of localized death of cells associated with the presence of the tumor.
39	Performance status score: Karnofsky score	☐ 100: Normal; no complaints ☐ 90: Able to carry out 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 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; requires hospitalization ☐ 10: Moribund; fatal processes progressing rapidly ☐ 0: Dead ☐ Unknown ☐ Not evaluated	2003853	Indicate the score from the Karnofsky Performance status scale, representing the functional capabilities of a person.
40	Number of days from index date to the date initial score obtained for the Karnofsky performance status scale	☐ _____	3479270	Provide the number of days from the index date to the date that the Karnofsky performance status assessment was performed.
41	Performance status score: Eastern Cooperative Oncology Group	☐ 0: Asymptomatic ☐ 1: Symptomatic but fully ambulatory ☐ 2: Symptomatic; in bed less than 50% of the day ☐ 3: Symptomatic; in bed more than 50% of the day but not bed-ridden ☐ 4: Bed-ridden ☐ 5: Dead ☐ Unknown ☐ Not evaluated	88	Indicate the ECOG functional performance status of the patient/participant.
42	Number of days from index date to the date initial score obtained for the ECOG performance status scale	_____	3479270	Provide the number of days from the index date to the date that the ECOG performance status assessment was performed.
Primary Tumor Clinical Molecular Characterization				
43	Was IDH1/2 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6062597	Indicate whether mutation analysis of IDH1 or IDH2 was performed. ***Note: If not performed, skip to Question 47.***
44	Was a mutation in IDH1/2 identified?	☐ Yes ☐ No	6002200	Indicate whether an IDH1 or IDH2 mutation was identified at testing. ***Note: If mutation was not identified, skip to Question 47.***
45	What method was used to identify the mutation?	☐ Cancer hotspot panel ☐ Next generation targeted sequencing ☐ Whole exome sequencing ☐ Other (specify)	6003729	Specify the method used to identify the mutation(s). ***Note: If the mutation identification method is not listed, proceed to Question 45a, otherwise, skip to Question 46.***
45a	Other mutation identification method	_____	6002204	If the mutation identification method is not included in the provided list, specify the method used to identify mutation(s).



Enrollment: Glioblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
46	If IDH1/2 mutation identified, which one?	☐ IDH1 R132H ☐ IDH1 R132C ☐ IDH1 R132S ☐ IDH1 R132G ☐ IDH1 R132L ☐ IDH2 R172W ☐ IDH2 R172K ☐ IDH2 R172M ☐ Other (specify)	6002206	Select the mutation identified in IDH1/2. ***Note: If the IDH1/2 mutation is not listed, proceed to Question 46a, otherwise, skip to Question 47.***
46a	Other IDH1/2 mutation	_____	6002207	If the mutation in IDH1/2 is not included in the provided list, specify the mutation in IDH1/2.
47	Was IDH1 R132H IHC performed?	☐ Yes ☐ No ☐ Unknown	6062408	Indicate whether immunohistochemistry for IDH1 R132H was performed. ***Note: If not performed, skip to Question 49.***
48	IDH1 R132H expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063674	Indicate the expression of IDH1 R132H as determined by immunohistochemistry (IHC).
49	MGMT promoter methylation status	☐ Methylated ☐ Partially methylated ☐ Unmethylated ☐ Indeterminate ☐ Not available	2799251	Indicate the methylation status of the MGMT promoter per testing results.
50	MMR status	☐ Evidence of MMR mutation by sequencing ☐ Evidence of MMR protein loss by IHC ☐ MMR loss evidence hypermutation phenotype (>10 mutations/Mb) ☐ No evidence of MMR alteration ☐ Not performed	6002208	Indicate the patient's Mismatch Repair (MMR) gene mutation status.
Primary Tumor Sample Information				
51	Are you submitting a primary tumor tissue sample for this case?	☐ Yes ☐ No		***If yes, proceed to question 52, otherwise, skip to Question 68.***
52	Primary tumor biospecimen ordinal	_____	6584265	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number should be "1".***
53	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
54	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
55	Sample represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this primary tumor specimen represent the PRIMARY DIAGNOSIS for this Case ID3? ***Note: If no, continue to Question 56, otherwise, skip to Question 57.***
56	Specify the ICD-10 code	_____	3226287	Provide the ICD-10 code for the primary tumor used to generate the model submitted to HCMI.
57	Tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the tumor tissue sample collected for molecular characterization.
58	Anatomic Site of tumor from which Model was Derived	☐ Brain ☐ Other (specify)	6033148	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI. ***Note: If the tissue or organ of origin is not listed, proceed to Question 58a. Otherwise, skip to Question 59.***



Enrollment: Glioblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
58a	Other anatomic site from which the tumor was obtained	_____	5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.
59	Method of cancer sample procurement	☐ Biopsy ☐ Subtotal resection ☐ Gross total resection ☐ Other method (specify)	3103514	Provide the procedure performed to obtain the primary tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 59a, otherwise, skip to Question 60.***
59a	Specify the other method of tumor sample procurement	_____	2006730	Specify the procedure performed to obtain the primary tumor tissue, if not included in the previous list.
60	Number of days from index date to date of tumor sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the tumor tissue submitted for HCMI.
61	Tumor tissue type	☐ Primary ☐ Additional Primary ☐ NOS	3288124	Provide the primary tumor tissue type for this sample.
Primary Tumor Model Information				
62	Primary model biospecimen ordinal	_____	6594596	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number is expected to be "1".***
63	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
64	BPC submitter ID (if available)		6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
65	Model represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this MODEL represent the PRIMARY DIAGNOSIS for this Case ID3?
66	Model's primary tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the PRIMARY TUMOR TISSUE from which this model is derived.
67	Model's primary tumor biospecimen ordinal	_____	6584265	Enter the biospecimen ordinal of the PRIMARY TUMOR TISSUE from which this model is derived.
Treatment Information				
68	History of neoadjuvant treatment	☐ No ☐ Yes; radiation prior to resection ☐ Yes; pharmaceutical treatment prior to resection ☐ Yes; both radiation and pharmaceutical treatment prior to resection ☐ Unknown	3382737	Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment. ***Note: Radiation therapy is addressed in Questions 76-77. Pharmaceutical therapy is addressed in Questions 69-75.***
69	Neoadjuvant chemotherapy type	☐ Cytotoxic chemotherapy ☐ Hormonal ☐ Immunotherapy (cellular and immune checkpoint) ☐ Targeted therapy (small molecule inhibitors and targeted antibodies) ☐ Not applicable	5832928	Select all neoadjuvant chemotherapy types that were administered to the patient. ***Note: Cytotoxic chemotherapy is addressed in Questions 70-71. Immunotherapy is addressed in Questions 72-73. Targeted therapy is addressed in Questions 74-75.***



Enrollment: Glioblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
70	Neoadjuvant chemotherapeutic regimen	☐ Bevacizumab ☐ Carboplatin ☐ Irinotecan ☐ Lomustine ☐ Temozolomide ☐ Vincristine ☐ Vorinostat ☐ Other (specify)	2853313	Select all chemotherapeutics used for neoadjuvant therapy. ***Note: If neoadjuvant chemotherapy was not given, skip to Question 72. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 70a, otherwise, skip to Question 71.***
70a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapies administered.
71	Days to neoadjuvant chemotherapy treatment from index date	_____	5102411	Provide the number of days from index date to the date of treatment with neoadjuvant chemotherapy.
72	Immunotherapy name, specify	_____	2953828	Provide the name of the immunotherapy administered to the patient. ***Note: If immunotherapy was not administered, skip to Question 74.***
73	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
74	Specify targeted therapy	_____	4308476	Provide the name of the targeted therapy administered to the patient. ***Note: If targeted therapy was not administered, skip to Question 76.***
75	Days to targeted therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with targeted therapy.
76	Radiation therapy administered type	☐ 2D conventional ☐ 3D conformal ☐ Brachytherapy HDR ☐ Brachytherapy LDR ☐ IMRT ☐ Proton Beam ☐ Stereotactic Body RT ☐ Stereotactic Radiosurgery ☐ WBRT ☐ Other (specify) ☐ Unspecified ☐ Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. ***Note: If radiation therapy was not administered, proceed to Question 78. If the radiation therapy is not listed, proceed to Question 76a, otherwise, skip to Question 77.***
76a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
77	Days to radiation treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with radiation therapy.
Metastatic/Recurrent Tumor Biospecimen Information				
78	Are you submitting a metastatic/recurrent tumor tissue sample?	☐ Yes ☐ No		Indicate whether a metastatic/ recurrent tumor biospecimen was collected for this ID3 case. ***Note: If yes, proceed to Question 79, otherwise, skip to Question 148.***
79	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1", the second should be number "2", etc.***
80	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
81	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.



Enrollment: Glioblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
82	Metastatic/recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
83	Number of days from index date to date of diagnosis of metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic/recurrent disease.
84	Method of metastatic/ recurrent cancer sample procurement	☐ Biopsy ☐ Subtotal resection ☐ Gross total resection ☐ Other (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 84a, otherwise, skip to Question 85.***
84a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
85	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
86	Metastatic/recurrent site	☐ Brain ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 86a, otherwise, skip to Question 87.***
86a	Other metastatic/ recurrent site	_____	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
87	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
88	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
89	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
90	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
91	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
92	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
93	Is the patient still receiving treatment?	_____	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.



Enrollment: Glioblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
94	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
95	Is necrosis present?	☐ Yes ☐ No ☐ Unknown	64740	Indicate if there is evidence of localized death of cells associated with the presence of the tumor.
96	Performance status score: Karnofsky score	☐ 100: Normal; no complaints ☐ 90: Able to carry out 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 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; requires hospitalization ☐ 10: Moribund; fatal processes progressing rapidly ☐ 0: Dead ☐ Unknown ☐ Not evaluated	2003853	Indicate the score from the Karnofsky Performance status scale, representing the functional capabilities of a person.
97	Number of days from index date to the date initial score obtained for the Karnofsky performance status scale	_____	3479270	Provide the number of days from the index date to the date that the Karnofsky performance status assessment was performed.
98	Performance status score: Eastern Cooperative Oncology Group	☐ 0: Asymptomatic ☐ 1: Symptomatic but fully ambulatory ☐ 2: Symptomatic; in bed less than 50% of the day ☐ 3: Symptomatic; in bed more than 50% of the day but not bed-ridden ☐ 4: Bed-ridden ☐ 5: Dead ☐ Unknown ☐ Not evaluated	88	Indicate the ECOG functional performance status of the patient/participant.
99	Number of days from index date to the date initial score obtained for the ECOG performance status scale	_____	3479270	Provide the number of days from the index date to the date that the ECOG performance status assessment was performed.
Metastatic/Recurrent Tumor Sample: Clinical Molecular Analyses				
100	Was IDH1/2 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6062597	Indicate whether mutation analysis of IDH1 or IDH2 was performed. ***Note: If not performed, skip to Question 104.***
101	Was a mutation in IDH1/2 identified?	☐ Yes ☐ No	6002200	Indicate whether an IDH1 or IDH2 mutation was identified at testing. ***Note: If mutation was not identified, skip to Question 104.***
102	What method was used to identify the mutation?	☐ Cancer hotspot panel ☐ Next generation targeted sequencing ☐ Whole exome sequencing ☐ Other (specify)	6003729	Specify the method used to identify the mutation(s). ***Note: If the mutation identification method is not listed, proceed to Question 102a, otherwise, skip to Question 103.***



Enrollment: Glioblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
102a	Other mutation identification method	_____	6002204	If the mutation identification method is not included in the provided list, specify the method used to identify mutation(s).
103	If IDH1/2 mutation identified, which one?	☐ IDH1 R132H ☐ IDH1 R132C ☐ IDH1 R132S ☐ IDH1 R132G ☐ IDH1 R132L ☐ IDH2 R172W ☐ IDH2 R172K ☐ IDH2 R172M ☐ Other (specify)	6002206	Select the mutation identified in IDH1/2. ***Note: If the IDH1/2 mutation is not listed, proceed to Question 103a, otherwise, skip to Question 104.***
103a	Other IDH1/2 mutation	_____	6002207	If the mutation in IDH1/2 is not included in the provided list, specify the mutation in IDH1/2.
104	Was IDH1 R132H IHC performed?	☐ Yes ☐ No ☐ Unknown	6062408	Indicate whether immunohistochemistry for IDH1 R132H was performed. ***Note: If not performed, skip to Question 106.***
105	IDH1 R132H expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063674	Indicate the expression of IDH1 R132H as determined by immunohistochemistry (IHC).
106	MGMT promoter methylation status	☐ Methylated ☐ Partially methylated ☐ Unmethylated ☐ Indeterminate ☐ Not available	2799251	Indicate the methylation status of the MGMT promoter per testing results.
107	MMR status	☐ Evidence of MMR mutation by sequencing ☐ Evidence of MMR protein loss by IHC ☐ MMR loss evidence hypermutation phenotype (>10 mutations/Mb) ☐ No evidence of MMR alteration ☐ Not performed	6002208	Indicate the patient's Mismatch Repair (MMR) gene mutation status.
Additional Metastatic/Recurrent Tumor Biospecimen Information (if applicable)				
108	Are you submitting an additional metastatic/ recurrent tumor tissue sample?	☐ Yes ☐ No		A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen. ***Note: If yes, proceed to Question 109, otherwise, skip to Question 138.***
109	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. The first biospecimen should be number "1," the second should be number "2," etc.
110	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
111	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.



Enrollment: Glioblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
112	Metastatic/recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
113	Number of days from index date to date of diagnosis of additional metastasis/recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of additional metastatic/recurrent disease.
114	Method of metastatic/ recurrent cancer sample procurement	☐ Biopsy ☐ Subtotal resection ☐ Gross total resection ☐ Other (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 114a, otherwise, skip to Question 115.***
114a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
115	Number of days from index date to date of metastatic/recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
116	Metastatic/recurrent site	☐ Brain ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 116a, otherwise, skip to Question 117.***
116a	Other metastatic/ recurrent site	_____	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
117	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
118	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
119	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
120	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
121	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
122	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.



Enrollment: Glioblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
123	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
124	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
125	Is necrosis present?	☐ Yes ☐ No ☐ Unknown	64740	Indicate if there is evidence of localized death of cells associated with the presence of the tumor.
126	Performance status score: Karnofsky score	☐ 100: Normal; no complaints ☐ 90: Able to carry out 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 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; requires hospitalization ☐ 10: Moribund; fatal processes progressing rapidly ☐ 0: Dead ☐ Unknown ☐ Not evaluated	2003853	Indicate the score from the Karnofsky Performance status scale, representing the functional capabilities of a person.
127	Number of days from index date to the date initial score obtained for the Karnofsky performance status scale	_____	3479270	Provide the number of days from the index date to the date that the Karnofsky performance status assessment was performed.
128	Performance status score: Eastern Cooperative Oncology Group	☐ 0: Asymptomatic ☐ 1: Symptomatic but fully ambulatory ☐ 2: Symptomatic; in bed less than 50% of the day ☐ 3: Symptomatic; in bed more than 50% of the day but not bed-ridden ☐ 4: Bed-ridden ☐ 5: Dead ☐ Unknown ☐ Not evaluated	88	Indicate the ECOG functional performance status of the patient/participant.
129	Number of days from index date to the date initial score obtained for the ECOG performance status scale	_____	3479270	Provide the number of days from the index date to the date that the ECOG performance status assessment was performed.
Additional Metastatic/Recurrent Tumor Sample: Clinical Molecular Analyses				
130	Was IDH1/2 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6062597	Indicate whether mutation analysis of IDH1 or IDH2 was performed. ***Note: If not performed, skip to Question 134.***
131	Was a mutation in IDH1/2 identified?	☐ Yes ☐ No	6002200	Indicate whether an IDH1 or IDH2 mutation was identified at testing. ***Note: If mutation was not identified, skip to Question 134.***



Enrollment: Glioblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
132	What method was used to identify the mutation?	☐ Cancer hotspot panel ☐ Next generation targeted sequencing ☐ Whole exome sequencing ☐ Other (specify)	6003729	Specify the method used to identify the mutation(s). ***Note: If the mutation identification method is not listed, proceed to Question 132a, otherwise, skip to Question 133.***
132a	Other mutation identification method	_____	6002204	If the mutation identification method is not included in the provided list, specify the method used to identify mutation(s).
133	If IDH1/2 mutation identified, which one?	☐ IDH1 R132H ☐ IDH2 R172W ☐ IDH1 R132C ☐ IDH2 R172K ☐ IDH1 R132S ☐ IDH2 R172M ☐ IDH1 R132G ☐ Other (specify) ☐ IDH1 R132L	6002206	Select the mutation identified in IDH1/2. ***Note: If the IDH1/2 mutation is not listed, proceed to Question 133a, otherwise, skip to Question 134.***
133a	Other IDH1/2 mutation	_____	6002207	If the mutation in IDH1/2 is not included in the provided list, specify the mutation in IDH1/2.
134	Was IDH1 R132H IHC performed?	☐ Yes ☐ No ☐ Unknown	6062408	Indicate whether immunohistochemistry for IDH1 R132H was performed. ***Note: If not performed, skip to Question 135.***
135	IDH1 R132H expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063674	Indicate the expression of IDH1 R132H as determined by immunohistochemistry (IHC).
136	MGMT promoter methylation status	☐ Methylated ☐ Partially methylated ☐ Unmethylated ☐ Indeterminate ☐ Not available	2799251	Indicate the methylation status of the MGMT promoter per testing results.
137	MMR status	☐ Evidence of MMR mutation by sequencing ☐ Evidence of MMR protein loss by IHC ☐ MMR loss evidence hypermutation phenotype (>10 mutations/Mb) ☐ No evidence of MMR alteration ☐ Not performed	6002208	Indicate the patient's Mismatch Repair (MMR) gene mutation status.
Metastatic/Recurrent Tumor Model Information				
138	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
139	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
140	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
141	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
142	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Additional Metastatic/Recurrent Biospecimen Tumor Model Information (if applicable)				
143	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence.

Enrollment: Glioblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

				Note: The first biospecimen should be number "1," the second should be number "2," etc.
144	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
145	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
146	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
147	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Other Biospecimen Information				
148	Are you submitting an OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an OTHER tissue sample (e.g. pre-malignant, non-malignant, or dysplastic tissue, etc.) was collected for HCMI for this case. ***Note: If yes, proceed to Question 149.***
149	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
150	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
151	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
152	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
153	Other method of cancer sample procurement	☐ Biopsy ☐ Subtotal resection ☐ Gross total resection ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 153a, otherwise, skip to Question 154.***
153a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
154	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
155	Tissue type	☐ Non-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 155a, otherwise, skip to Question 156.***



Enrollment: Glioblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
155a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
156	Anatomic site of OTHER tissue	☐ Brain ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 156a, otherwise, skip to Question 157.***
156a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.
157	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
158	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Additional OTHER biospecimen Information (if applicable)				
159	Are you submitting an additional OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an additional OTHER tissue sample (pre-malignant, non-malignant, or dysplastic tissue, etc.) is being submitted for HCMI for this case. ***Note: If yes, proceed to Question 160. If no, proceed to Question 170.***
160	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
161	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
162	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
163	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
164	Other method of cancer sample procurement	☐ Biopsy ☐ Subtotal resection ☐ Gross total resection ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 164a, otherwise, skip to Question 165.***
164a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
165	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
166	Tissue type	☐ Non-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 166a, otherwise, skip to Question 167.***
166a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.



Enrollment: Glioblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
167	Anatomic site of OTHER tissue	☐ Brain ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 167a, otherwise, skip to Question 168.***
167a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.
168	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
169	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Other Tissue Model Information				
170	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
171	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
172	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
173	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
174	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.
Additional Other Tissue Model Information (if applicable)				
175	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
176	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
177	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
178	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
179	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.



Enrollment: Head and Neck

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Form Notes: An Enrollment Form should be completed for each HCMI case upon qualification notice from Leidos. All information provided on this form should include activity from the Date of Initial Pathologic Diagnosis to the most recent Date of Last Contact with the patient.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	☐ Initial pathologic diagnosis ☐ Sample procurement ☐ First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.
Patient Information				
4	Gender	☐ Male ☐ Female ☐ Unspecified	2200604	Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
5	Height	_____	649	Provide the patient's height, in centimeters.
6	Weight	_____	651	Provide the patient's weight, in kilograms.
7	Body mass index (BMI)	_____	2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
8	Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown ☐ Not reported	2192199	Provide the patient's race using the defined categories. **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 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. **Black or African American:** A person having origins in any of the black racial groups of Africa. **Native Hawaiian or other Pacific Islander:** A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island. **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
9	Ethnicity	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Not reported	2192217	Provide the patient's ethnicity using the defined categories. **Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. **Not Hispanic or Latino:** A person not meeting the definition of Hispanic or Latino.



Enrollment: Head and Neck

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
10	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.
11	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. ***Note: If the patient's age is greater than 32,872 days (90 years), please enter 32,872.***
12	Year of birth	_____	2896954	Provide the year of the patient's birth. If the patient was born prior to 1928, insert the date 1928.
13	Family history of cancer	☐ Same ☐ Different ☐ None ☐ Unknown	5832923	Has a first-degree relative of the patient been diagnosed with a cancer of the same or a different type?
14	Smoking history	☐ Lifelong non-smoker (<100 cigarettes smoked in a lifetime) ☐ Current smoker (includes daily and non-daily smokers) ☐ Current reformed smoker (duration not specified) ☐ Current reformed smoker for >15 years ☐ Current reformed smoker for ≤15 years	2181650	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories. ***Note: If the patient has a smoking history, proceed to Question 15, otherwise, skip to Question 17.***
15	Number pack years smoked	_____	2955385	Indicate the number of pack years smoked. (Numeric computed value to represent lifetime tobacco exposure defined as number of cigarettes smoked per day x number of years smoked divided by 20.)
16	Tobacco smoking quit year	_____	2228610	Indicate the year in which the participant quit smoking.
17	Alcohol exposure intensity	☐ Not evaluated ☐ Lifetime non-drinker ☐ Non-drinker ☐ Daily drinker ☐ Weekly drinker	3457767	Select the patient's current level of alcohol use as self-reported by the patient. ***Note: If the patient drinks alcohol, proceed to Question 18, otherwise, skip to Question 21.***
18	Alcohol type	☐ Beer ☐ Liquor ☐ Wine ☐ Other (specify)	2201970	Select all types of alcohol consumed as self-reported by the patient.
18a	Specify other alcohol type	_____	6788013	If not included in the previous list, provide all types of alcohol consumed as self-reported by the patient.
19	Amount of alcohol consumption per day	_____drinks per day	3124961	Provide the average number of alcoholic beverages that the patient reports consuming per day.
20	Amount of alcohol consumption per week	_____drinks per week	3114013	Provide the average number of days each week that the patient consumes an alcoholic beverage.
21	Did the patient ever use smokeless tobacco (including chewing tobacco and snuff) regularly for a period of six weeks or more?	☐ Yes ☐ No ☐ Unknown	3624720	Indicate whether or not the patient used smokeless tobacco regularly for a period of six weeks or more. ***Note: If the patient used smokeless tobacco, proceed to Question 22, otherwise, skip to Question 25.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
22	If the patient used smokeless tobacco (including chewing tobacco and snuff) regularly for at least six weeks, on average how many times per day did they use?	_____	3624721	Indicate how many times per day an individual regularly using smokeless tobacco for at least six weeks chewed or used snuff.
23	If the patient used smokeless tobacco (including chewing tobacco and snuff) regularly for at least six weeks, how old were they when they started using?	_____	3624722	Provide the age (in years) the patient began chewing tobacco and/or using snuff.
24	If the patient used smokeless tobacco (including chewing tobacco and snuff) regularly for at least six weeks, how old were they when they quit using?	_____	3624723	Provide the age (in years) the patient stopped chewing tobacco and/or using snuff.
25	Is the patient currently using marijuana?	☐ Yes ☐ No ☐ Unknown	6788017	Indicate whether the patient is currently using marijuana. ***Note: If the patient used marijuana, proceed to Question 26, otherwise, skip to Question 27.***
26	Marijuana usage per week	_____	6788018	Indicate the total number of times the patient used marijuana each week.
27	Did the patient ever use e-cigarettes regularly for a period of six weeks or more?	☐ Yes ☐ No ☐ Unknown	6788019	Indicate whether the patient has ever used electronic cigarettes regularly for a period of six weeks or more. ***Note: If the patient used e-cigarettes, proceed to Question 28, otherwise, skip to Question 29.***
28	Number of days e-cigarettes were used in the last 30 days	_____	6788020	Indicate the number of days that the patient used electronic cigarettes within the last 30 days.
29	Asbestos exposure?	☐ Yes ☐ No ☐ Unknown	1253	Specify if the patient has been exposed to asbestos.
30	Is the patient HIV-positive?	☐ Yes ☐ No ☐ Unknown	3196353	Indicate whether the patient has been diagnosed with Human Immunodeficiency Virus (HIV). ***Note: If the patient is HIV-positive, proceed to Question 31, otherwise, skip to Question 32.***
31	CD4 count	_____	4182751	Indicate the result of the procedure used to determine the number of CD4+ T-cells in the patient's sample.
32	Metastasis at diagnosis assessment status	☐ Metastatic ☐ Non-metastatic (confirmed) ☐ Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor. ***Note: If metastatic at diagnosis, proceed to Question 33, otherwise, skip to Question 34.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
33	Metastatic site(s) at diagnosis	☐ Lung ☐ Bone ☐ Liver ☐ Mediastinum ☐ Bone marrow ☐ Lymph node(s): non-regional ☐ Lymph node(s): regional ☐ Other (specify)	3108271	Indicate the site(s) of metastasis at the time of diagnosis of the primary tumor. ***Note: If the anatomic site of tumor tissue is not listed, proceed to Question 33a, otherwise, skip to Question 34.***
33a	Specify metastatic site(s)	_____	3128033	If the site of metastasis is not included on the provided list, specify the site of metastasis.
Biospecimen Information				
34	Tissue sample type(s) collected for HCMI for this case	☐ Normal tissue ☐ Primary tumor ☐ Metastatic ☐ Recurrent ☐ Other tissue	2006911	Please select all the tissue sample types submitted for HCMI with this case.
35	Number of NORMAL tissues biospecimens collected for HCMI for this case	_____	6584256	Please provide the number of normal tissue specimens obtained for HCMI for this case. ***Note: This number is expected to be 1.***
36	Number of PRIMARY cancer tissue biospecimens collected for HCMI model development for this case	_____	6584257	Please provide the number of primary tumor specimens obtained for HCMI for this case. ***Note: A single primary tumor biospecimen obtained that is portioned for both sequencing and model generation counts as 1 single primary tumor specimen. This number is expected to be 1.***
37	Number of METASTATIC/ RECURRENT cancer tissue biospecimens collected for HCMI model development for this case	_____	6584258	Please provide the number of metastatic and/or recurrent cancer biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
38	Number of OTHER tissue biospecimens collected for HCMI model development for this case	_____	6584259	Please provide the number of pre-malignant, non-malignant, or dysplastic tissue biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
39	Total number of tissue biospecimens collected for HCMI for this case	_____	6584271	Please provide the total number of tissue biospecimens collected for HCMI for this case. ***Note: This number should be the sum of the normal, primary tumor, metastatic/ recurrent tumor, and other biospecimen counts above.***
Normal Control Information				
40	Normal tissue biospecimen ordinal	_____	6584264	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
41	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
42	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
43	Type of normal control	☐ Whole blood ☐ Buccal cells ☐ Buffy coat ☐ Lymphocytes ☐ Extracted DNA from blood ☐ Extracted DNA from saliva ☐ Extracted DNA from buccal cells ☐ Extracted DNA from normal tissue ☐ Adjacent normal tissue (specify) ☐ Contralateral normal tissue (specify) ☐ FFPE non-neoplastic tissue (specify) ☐ Non-neoplastic tissue (specify)	3081936	Indicate the type of normal control submitted for this case.
44	Anatomic site of normal tissue	☐ Lip ☐ Oral tongue, anterior ☐ Skin ☐ Oropharynx ☐ Nasopharynx ☐ Hypopharynx ☐ Supraglottis ☐ Glottis ☐ Subglottis ☐ Nasal cavity ☐ Paranasal sinus(es) ☐ Parotid gland ☐ Submandibular gland ☐ Sublingual gland ☐ Other (specify) ☐ Not applicable	4132152	If non-neoplastic tissue was submitted as the normal control, select the anatomic site of the normal tissue. ***Note: If the anatomic site of normal tissue is not listed, proceed to Question 44a, otherwise, skip to Question 45.***
44a	Other anatomic site of normal tissue	_____	3288189	If non-neoplastic tissue, adjacent tissue, or normal tissue from another anatomic site was submitted as the normal control, provide the anatomic site of the normal tissue.
45	Distance from tumor to normal control tissue (if not blood)	☐ Adjacent (< or = 2cm) ☐ Distal (>2cm) ☐ Unknown ☐ Not applicable	3088708	Indicate the distance from the site of normal tumor collection to the primary tumor. ***Note: If normal tissue was not submitted, select 'Not applicable'.***
46	Normal tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the normal tissue sample collected for molecular characterization.
Primary Tumor Biospecimen Information				
47	Head and neck cancer region	☐ Lip and Oral cavity ☐ Pharynx ☐ Larynx ☐ Paranasal sinuses and nasal cavity ☐ Salivary glands	2179718	Select the anatomic site of origin for the head and neck cancer in the patient.
48	ICD-10 code for primary tumor	☐ C00.0 ☐ C00.1 ☐ C00.2 ☐ C00.3 ☐ C00.4 ☐ C00.5 ☐ C00.6 ☐ C00.8 ☐ C03.9 ☐ C04.0 ☐ C04.1 ☐ C04.8 ☐ C04.9 ☐ C05.0 ☐ C05.1 ☐ C05.2 ☐ C08.9 ☐ C09.0 ☐ C09.1 ☐ C09.8 ☐ C09.9 ☐ C10.1 ☐ C10.2 ☐ C10.3 ☐ C13.2 ☐ C13.8 ☐ C13.9 ☐ C14.0 ☐ C30.0 ☐ C31.0 ☐ C31.1 ☐ C31.2	3226287	Provide the ICD-10 code for the primary tumor as used to generate the ID3 for this subject. ***Note: If the ICD-10 code is not listed, proceed to 48a, otherwise, skip to Question 49.***



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		☐ C00.9 ☐ C01 ☐ C02.0 ☐ C02.1 ☐ C02.2 ☐ C02.3 ☐ C02.4 ☐ C02.8 ☐ C02.9 ☐ C03.0 ☐ C03.1 ☐ C05.8 ☐ C05.9 ☐ C06.0 ☐ C06.1 ☐ C06.2 ☐ C06.8 ☐ C06.9 ☐ C07 ☐ C08.0 ☐ C08.1 ☐ C08.8 ☐ C10.8 ☐ C10.9 ☐ C11.0 ☐ C11.1 ☐ C11.2 ☐ C11.3 ☐ C11.8 ☐ C11.9 ☐ C12 ☐ C13.0 ☐ C13.1 ☐ C31.3 ☐ C31.8 ☐ C31.9 ☐ C32.0 ☐ C32.1 ☐ C32.2 ☐ C32.3 ☐ C32.8 ☐ C32.9 ☐ Other (specify)		
48a	Other ICD-10 code for primary tumor	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.
49	Tumor morphology	☐ 8070/3 ☐ 8041/3 ☐ 8051/3 ☐ 8052/3 ☐ 8073/3 ☐ 8074/3 ☐ 8075/3 ☐ 8082/3 ☐ 8083/3 ☐ 8147/3 ☐ 8200/3 ☐ 8310/3 ☐ 8340/4 ☐ 8430/3 ☐ 8500/3 ☐ 8523/3 ☐ 8525/3 ☐ 8550/3 ☐ 8560/3 ☐ 8562/3 ☐ 8720/3 ☐ 8982/3 ☐ Other (specify)	3226275	Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor. ***Note: If the ICD-O-3 histology code of the primary tumor is not listed, proceed to Question 49a, otherwise, skip to Question 50.***
49a	Specify other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.
50	Tissue or organ of origin	☐ Lip ☐ Oral cavity ☐ Pharynx ☐ Larynx ☐ Paranasal sinuses ☐ Nasal cavity ☐ Salivary gland ☐ Other (specify)	3427536	Using the patient's pathology/ laboratory report, select the primary site of the disease. ***Note: If the primary site of the disease is not listed, proceed to Question 50a, otherwise skip to Question 51.***
50a	Other tissue or organ of origin	_____	5946219	If the primary site of the disease is not included on the previous list, provide the primary site of the disease.
51	Histological type	☐ Head and neck cancer ☐ Other (specify)	3081932	Select the surgical pathology text description of the histological tumor type. ***Note: If the histological tumor type is not listed, proceed to Question 51a, otherwise, skip to Question 52.***
51a	Other histological type	_____	3294805	If the traditional surgical pathology text description of the histological tumor type is not included on the previous list, specify the histological type.
52	Histological subtype	☐ Acantholytic squamous cell carcinoma ☐ Acinic cell carcinoma ☐ Adenocarcinoma, non-salivary gland type ☐ Adenocarcinoma, NOS (specify low, intermediate, or high grade) ☐ Adenoid cystic carcinoma (specify tubular, cribriform, or solid pattern) ☐ Adenosquamous carcinoma ☐ Basal cell adenocarcinoma ☐ Basaloid squamous cell carcinoma ☐ Biphenotypic sinonasal sarcoma	3081934	Using the patient's pathology/laboratory report, select the histological subtype of the primary tumor. ***Note: If the histological subtype is not listed, proceed to Question 52a, otherwise, skip to Question 53.***



		☐ Carcinoma cuniculatum ☐ Carcinosarcoma ☐ Clear cell carcinoma ☐ Epithelial-myoepithelial carcinoma ☐ HPV-mediated squamous cell carcinoma ☐ HPV-unrelated squamous cell carcinoma ☐ Hypopharyngeal squamous cell carcinoma ☐ Intestinal adenocarcinoma, colonic pattern ☐ Intestinal adenocarcinoma, mixed pattern ☐ Intestinal adenocarcinoma, mucinous pattern ☐ Intestinal adenocarcinoma, papillary pattern ☐ Intestinal adenocarcinoma, solid pattern ☐ Intraductal carcinoma, (specify low, intermediate, or high grade) ☐ Large cell neuroendocrine carcinoma, HPV - ☐ Large cell neuroendocrine carcinoma, HPV + ☐ Lymphoepithelial carcinoma ☐ Moderately differentiated neuroendocrine carcinoma ☐ Mucoepidermoid carcinoma (specify low, intermediate, or high grade) ☐ Mucosal melanoma ☐ Myoepithelial carcinoma ☐ Nasopharyngeal papillary adenocarcinoma ☐ Non-intestinal adenocarcinoma, (specify low, intermediate, or high grade) ☐ NUT carcinoma ☐ Oncocytic carcinoma ☐ Oropharyngeal squamous cell carcinoma, HPV status unknown ☐ Papillary squamous cell carcinoma ☐ Polymorphous adenocarcinoma, classic (specify low, intermediate, or high grade) ☐ Polymorphous adenocarcinoma, classic, (specify low, intermediate, or high grade) ☐ Polymorphous adenocarcinoma, cribriform (specify low, intermediate, or high grade) ☐ Poorly differentiated carcinoma, large cell neuroendocrine ☐ Poorly differentiated carcinoma, small cell neuroendocrine ☐ Poorly differentiated carcinoma, undifferentiated ☐ Poorly differentiated neuroendocrine carcinoma, large cell ☐ Poorly differentiated neuroendocrine carcinoma, small cell ☐ Salivary duct carcinoma ☐ Sebaceous adenocarcinoma ☐ Secretory carcinoma ☐ Sinonasal undifferentiated carcinoma ☐ Small cell neuroendocrine carcinoma, HPV - ☐ Small cell neuroendocrine carcinoma, HPV + ☐ Spindle cell squamous cell carcinoma ☐ Squamous cell carcinoma, keratinizing ☐ Squamous cell carcinoma, nonkeratinizing ☐ Squamous cell carcinoma, primary ☐ Verrucous squamous cell carcinoma ☐ Well differentiated neuroendocrine carcinoma ☐ Well-differentiated neuroendocrine carcinoma		



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		☐ Other (specify)		
52a	Other histological subtype	_____	3124492	If the histological subtype for the primary tumor is not included in the provided list, specify the histological subtype.
53	For mucoepidermoid carcinoma, indicate the grade	☐ Low ☐ Intermediate ☐ High ☐ Unknown	6788058	Indicate the histologic grade of the Mucoepidermoid carcinoma.
54	For adenoid cystic carcinoma, indicate the pattern type	☐ Tubular ☐ Cribriform ☐ Solid	6788063	Indicate the morphological pattern of tumor growth for Adenoid cystic carcinoma.
55	For polymorphous adenocarcinoma, indicate the grade	☐ Low ☐ Intermediate ☐ High ☐ Unknown	6788059	Indicate the histologic grade of the polymorphous adenocarcinoma.
56	For adenocarcinoma, NOS, indicate the grade	☐ Low ☐ Intermediate ☐ High ☐ Unknown	6788060	Indicate the histologic grade of the adenocarcinoma, NOS.
57	For intraductal carcinoma, indicate the grade	☐ Low ☐ Intermediate ☐ High ☐ Unknown	6788061	Indicate the histologic grade of the intraductal carcinoma.
58	For non-intestinal adenocarcinoma, indicate the grade	☐ Low ☐ Intermediate ☐ High ☐ Unknown	6788062	Indicate the histologic grade of the non-intestinal adenocarcinoma.
59	Prior malignancy (of the same cancer type)	☐ Yes ☐ No ☐ Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
60	Prior malignancy (other cancer type)	☐ Yes ☐ No ☐ Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.
61	AJCC cancer staging edition	☐ 1st ☐ 2nd ☐ 3rd ☐ 4th ☐ 5th ☐ 6th ☐ 7th ☐ 8th	2722309	Select the AJCC staging handbook edition used to stage the patient's primary tumor.
62	Clinical stage group	☐ Stage 0 ☐ Stage I ☐ Stage II ☐ Stage III ☐ Stage IVA ☐ Stage IVB ☐ Stage IVC	3440332	Using the patient's pathology/laboratory report, select the clinical stage group of the primary tumor as defined by the American Joint Committee on Cancer (AJCC).
63	AJCC pathologic spread: Primary tumor (pT)	☐ Tx ☐ Tis ☐ T0 ☐ T1 ☐ T2 ☐ T3 ☐ T4 ☐ T4a ☐ T4b	3045435	Using the patient's pathology/laboratory report, select the code for the pathologic T (primary tumor) as defined by the American Joint Committee on Cancer (AJCC).
64	AJCC pathologic spread: Lymph nodes (pN)	☐ NX ☐ N0 ☐ N1 ☐ N2 ☐ N2a ☐ N2b ☐ N2c ☐ N3 ☐ N3a ☐ N3b	3203106	Using the patient's pathology/laboratory report, select the code for the pathologic N (nodal) as defined by the American Joint Committee on Cancer (AJCC).



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
65	AJCC pathologic spread: Distant metastases (pM)	☐ M0 ☐ M1 ☐ MX	3045439	Using the patient's pathology/laboratory report, select the code for the pathologic M (metastasis) as defined by the American Joint Committee on Cancer (AJCC).
66	Tumor stage (pathological)	☐ Stage 0 ☐ Stage I ☐ Stage II ☐ Stage III ☐ Stage IVA ☐ Stage IVB ☐ Stage IVC	3065862	Using the patient's pathology/laboratory report, in conjunction with the patient's medical record, select the stage as defined by the American Joint Committee on Cancer (AJCC).
67	For squamous cell carcinomas, tumor grade	☐ G1 ☐ G2 ☐ G3 ☐ GX	2785839	Using the patient's pathology/laboratory report, select the grade of the primary tumor.
68	For salivary gland head and neck cancers, select the grade	☐ Low grade ☐ Intermediate grade ☐ High grade	2785839	Using the patient's pathology/laboratory report, select the grade of the primary tumor.
Prognostic/Predictive/Lifestyle Features for Primary Tumor Prognosis or Responsiveness to Treatment				
69	Tumor laterality	☐ Right ☐ Left ☐ Bilateral ☐ Midline ☐ Not specified ☐ Not a paired site	827	For a tumor in a paired organ, designate the side of the body on which the tumor or cancer developed.
70	Tumor focality	☐ Unifocal ☐ Multifocal ☐ Cannot be determined	3174022	Indicate whether the tumor or cancer first developed in a single or multiple locations.
71	Tumor size (greatest dimension, cm)	_____cm	64215	Provide the length of the largest dimension/diameter of a tumor, in cm, regardless of anatomical plane.
72	Tumor depth of invasion (mm)	_____mm	2182144	Provide the measurement in mm of the depth of invasion of the tumor.
73	Lymphovascular invasion present?	☐ Yes ☐ No ☐ Indeterminate ☐ Unknown	64727	Indicate whether large vessel (vascular) invasion or small, thin-walled (lymphatic) invasion was detected in the primary tumor.
74	Perineural invasion present?	☐ Yes ☐ No ☐ Unknown	64181	Indicate whether perineural invasion or infiltration of tumor or cancer is present.
75	Number of positive lymph nodes	_____	89	Provide the number of lymph nodes with disease involvement.
76	Number of lymph nodes tested	_____	3	Provide the total number of lymph nodes tested for the presence of cancer cells.
77	Extranodal extension	☐ Present ☐ Absent ☐ Unknown	65043	Indicate whether extranodal extension of the cancer is present.
78	Residual tumor/margins	☐ RX (Presence of residual tumor cannot be addressed) ☐ R0 (No residual tumor) ☐ R1 (Microscopic residual tumor) ☐ R2 (Macroscopic residual tumor)	2608702	Indicate the status of the tissue margin following surgical resection.
79	Margin distance (mm)	_____mm	3915853	Provide the distance between the malignant neoplasm and the surgical margin in mm.
80	High-grade dysplasia in mucosal resection margins	☐ Present ☐ Absent ☐ Unknown	6788003	Indicate whether high-grade dysplasia was detected within the mucosal resection margins.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
81	Growth pattern of primary tumor	☐ Cohesive ☐ Non-adhesive	6788004	Indicate the type of growth pattern exhibited by the primary tumor.
82	Epstein-Barr virus infection	☐ Yes ☐ No ☐ Unknown	3626299	Indicate whether or not an Epstein-Barr virus infection occurred in the patient.
83	Was Epstein-Barr Virus (EBV) early mRNA ISH performed?	☐ Yes ☐ No ☐ Unknown	6788005	Indicate whether Epstein-Barr Virus early mRNA status was assessed using an in situ hybridization (ISH) assay.
84	Epstein-Barr Virus (EBV) early mRNA status by ISH	☐ Positive ☐ Negative ☐ Indeterminate	6788006	Indicate the Epstein-Barr Virus early mRNA status detected by an in situ hybridization staining method.
85	Was p16 IHC performed?	☐ Yes ☐ No ☐ Unknown	6690713	Indicate whether or not immunohistochemical analysis for a p16/CDKN2A mutation was performed. ***Note: If p16 IHC was performed, proceed to Question 86, otherwise, skip to Question 87.***
86	p16 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6690724	Indicate the status of the p16/CDKN2A protein expression using immunohistochemistry.
87	Was HPV-DNA ISH performed?	☐ Yes ☐ No ☐ Unknown	6788007	Indicate whether Human Papillomavirus DNA status was assessed using an in situ hybridization (ISH) assay. ***Note: If HPV-DNA ISH was performed, proceed to Question 88, otherwise, skip to Question 89.***
88	HPV-DNA status by ISH	☐ Positive ☐ Negative ☐ Indeterminate	6788008	Indicate the Human Papillomavirus DNA status as detected by an in situ hybridization staining method.
89	Was HPV-E6/E7 mRNA ISH performed?	☐ Yes ☐ No ☐ Unknown	6788009	Indicate whether Human Papillomavirus E6/E7 status was assessed using an in situ hybridization (ISH) assay. ***Note: If HPV-E6/E7 mRNA ISH was performed, proceed to Question 90, otherwise, skip to Question 91.***
90	HPV-E6/E7 mRNA status by ISH	☐ Positive ☐ Negative ☐ Indeterminate	6788010	Indicate the Human Papillomavirus E6/E7 mRNA status as detected by an in situ hybridization staining method.
91	Was HPV-DNA PCR performed?	☐ Yes ☐ No ☐ Unknown	6788011	Indicate whether or not Human Papillomavirus DNA status was assessed by polymerase chain reaction. ***Note: If HPV-DNA PCR was performed, proceed to Question 92, otherwise, skip to Question 93.***
92	HPV-DNA status by PCR	☐ Positive ☐ Negative ☐ Indeterminate	6788015	Indicate the Human Papillomavirus DNA status detected by reverse transcriptase-polymerase chain reaction method.
93	Was HPV-E6/E7 mRNA RT-PCR performed?	☐ Yes ☐ No ☐ Unknown	6788012	Indicate whether Human Papillomavirus E6/E7 mRNA status was assessed using a polymerase chain reaction assay. ***Note: If HPV-E6/E7 mRNA RT-PCR was performed, proceed to Question 94, otherwise, skip to Question 95.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
94	HPV-E6/E7 mRNA status by RT-PCR	☐ Positive ☐ Negative ☐ Indeterminate	6788016	Indicate the Human Papillomavirus E6/E7 mRNA status detected by reverse transcriptase-polymerase chain reaction method.
95	Additional pathologic findings	☐ Carcinoma in situ ☐ Colonization, bacterial ☐ Colonization, fungal ☐ Dysplasia, high grade ☐ Dysplasia, low grade ☐ Epithelial dysplasia ☐ Epithelial hyperplasia ☐ Hyperkeratosis ☐ Inflammation ☐ Keratinizing dysplasia, mild ☐ Keratinizing dysplasia, moderate ☐ Keratinizing dysplasia, severe (carcinoma in situ) ☐ None identified ☐ Nonkeratinizing dysplasia, mild ☐ Nonkeratinizing dysplasia, moderate ☐ Nonkeratinizing dysplasia, severe (carcinoma in situ) ☐ Sialadenitis ☐ Sinonasal papilloma ☐ Squamous metaplasia ☐ Squamous papilloma, solitary ☐ Squamous papillomatosis ☐ Tumor associated lymphoid proliferation ☐ Other (specify)	6790126	Indicate all additional pathologic findings present in the patient. ***Note: If the pathologic finding is not listed, proceed to Question 95a, otherwise, skip to Question 96.***
95a	Specify other additional pathologic findings	_____	6788022	If not included in the previous list, specify any additional pathologic findings.
Pharynx Cancer-specific Questions				
96	If tumor is in the pharynx, in which subregion?	☐ Nasopharynx ☐ Hypopharynx ☐ Oropharynx ☐ Not applicable	3380090	Indicate the subregion of the pharynx in which the patient's tumor is found.
97	Occupational exposure to wood dust	☐ Yes ☐ No ☐ Unknown	4193912	Indicate whether the patient was exposed to wood dust in the workplace.
Larynx Cancer-specific Questions				
98	Transglottic extension	☐ Present ☐ Not identified	6788023	Indicate whether a transglottic extension of the patient's laryngeal tumor was present.
Paranasal Sinuses and Nasal Cavity Cancer-specific Questions				
NUT Carcinoma-specific Questions				
99	Was NUT IHC performed?	☐ Yes ☐ No ☐ Unknown	6788024	Indicate whether NUTM1 protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If NUT IHC was performed, proceed to Question 100, otherwise, skip to Question 101.***
100	NUT expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6788028	Indicate the status of the NUTM1 protein expression using immunohistochemistry.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
101	Was NUT translocation analysis performed?	☐ Yes ☐ No ☐ Unknown	6788032	Indicate whether an analysis for translocation in the NUTM1 gene was performed. ***Note: If NUT translocation analysis was performed, proceed to Question 102, otherwise, skip to Question 104.***
102	Was a NUT translocation identified?	☐ Yes ☐ No	6788038	Indicate whether a NUTM1 chromosomal translocation was identified. ***Note: If a NUT translocation was identified, proceed to Question 103, otherwise, skip to Question 104.***
103	If translocation identified with NUT, which one?	☐ NUT-BRD4 ☐ Other translocation (specify)	6788044	Select the translocation identified with the NUTM1 gene. ***Note: If the NUT translocation is not listed, proceed to Question 103a, otherwise, skip to Question 104.***
103a	Specify other NUT translocation	_____	6788055	If not included in the previous list, provide the translocation identified with the NUTM1 gene.
Sinonasal Undifferentiated Carcinoma-specific Questions				
104	Was INI-1 IHC performed?	☐ Yes ☐ No ☐ Unknown	6788025	Indicate whether INI-1 (SMARCB1) protein expression by immunohisto-chemistry (IHC) analysis was performed. ***Note: If INI-1 IHC was performed, proceed to Question 105, otherwise, skip to Question 106.***
105	INI-1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6788029	Indicate the status of the INI-1 (SMARCB1) protein expression using immunohistochemistry.
Biphenotypic Sinonasal Sarcoma-specific Questions				
106	Was PAX3 translocation analysis performed?	☐ Yes ☐ No ☐ Unknown	6788033	Indicate whether an analysis for translocation in the PAX3 gene was performed. ***Note: If PAX3 translocation analysis was performed, proceed to Question 107, otherwise skip to question 109.***
107	Was a PAX3 translocation identified?	☐ Yes ☐ No	6788039	Indicate whether a PAX3 chromosomal translocation was identified. ***Note: If a PAX3 translocation was identified, proceed to Question 108, otherwise, skip to Question 109.***
108	If translocation identified with PAX3, which one?	☐ PAX3-MAML3 ☐ Other translocation (specify)	6788045	Select the translocation identified with the PAX3 gene. ***Note: If the PAX3 translocation is not listed, proceed to Question 108a, otherwise skip to Question 109.***
108a	Specify other PAX3 translocation	_____	6788050	If not included in the previous list, provide the translocation identified with the PAX3 gene.
Salivary Gland Cancer-specific Questions				
109	High grade transformation	☐ Present ☐ Not identified ☐ Not applicable	6788056	Indicate the high grade transformation status of the salivary gland tumor.
Clear Cell Carcinoma-specific Questions				
110	Was EWSR1 translocation analysis performed?	☐ Yes ☐ No ☐ Unknown	6788034	Indicate whether an analysis for translocation in the EWSR1 gene was performed. ***Note: If EWSR1 translocation analysis was performed, proceed to Question 111, otherwise, skip to Question 113.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
111	Was an EWSR1 translocation identified?	☐ Yes ☐ No	6788040	Indicate whether an EWSR1 chromosomal translocation was identified. ***Note: If an EWSR1 translocation was identified, proceed to Question 112, otherwise, skip to Question 113.***
112	If translocation identified with EWSR1, which one?	☐ EWSR1-ATF1 ☐ Other translocation	6788046	Select the translocation identified with the EWSR1 gene. ***Note: If the EWSR1 translocation is not listed, proceed to Question 112a, otherwise skip to Question 113.***
112a	Specify other EWSR1 translocation	_____	6788051	If not included in the previous list, provide the translocation identified with the EWSR1 gene.
Secretory Carcinoma-specific Questions				
113	Was ETV6 translocation analysis performed?	☐ Yes ☐ No ☐ Unknown	6788035	Indicate whether an analysis for translocation in the ETV6 gene was performed. ***Note: If ETV6 translocation analysis was performed, proceed to Question 114, otherwise, skip to Question 116.***
114	Was an ETV6 translocation identified?	☐ Yes ☐ No	6788041	Indicate whether an ETV6 chromosomal translocation was identified. ***Note: If an ETV6 translocation was identified, proceed to Question 115, otherwise, skip to Question 116.***
115	If translocation identified with ETV6, which one?	☐ ETV6-NTRK3 ☐ Other translocation (specify)	6788047	Select the translocation identified with the ETV6 gene. ***Note: If the ETV6 translocation is not listed, proceed to Question 115a, otherwise skip to Question 116.***
115a	Specify other ETV6 translocation	_____	6788052	If not included in the previous list, provide the translocation identified with the ETV6 gene.
Mucoepidermoid Carcinoma-specific Questions				
116	Was MAML2 translocation analysis performed?	☐ Yes ☐ No ☐ Unknown	6788036	Indicate whether an analysis for translocation in the MAML2 gene was performed. ***Note: If MAML2 translocation analysis was performed, proceed to Question 117, otherwise, skip to Question 119.***
117	Was a MAML2 translocation identified?	☐ Yes ☐ No	6788042	Indicate whether a MAML2 chromosomal translocation was identified. ***Note: If a MAML2 translocation was identified, proceed to Question 118, otherwise, skip to Question 119.***
118	If translocation identified with MAML2, which one?	☐ MAML2-CRTC1 ☐ MAML2-CRTC3 ☐ Other translocation (specify)	6788048	Select the translocation identified with the MAML2 gene. ***Note: If the MAML2 translocation is not listed, proceed to Question 118a, otherwise, skip to Question 119.***
118a	Specify other MAML2 translocation	_____	6788053	If not included in the previous list, provide the translocation identified with the MAML2 gene.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Adenoid Cystic Carcinoma-specific Questions				
119	Was MYB IHC performed?	☐ Yes ☐ No ☐ Unknown	6788026	Indicate whether MYB protein expression by immunohisto-chemistry (IHC) analysis was performed. ***Note: If MYB IHC was performed, proceed to Question 120, otherwise, skip to Question 121.***
120	MYB expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6788030	Indicate the status of the MYB protein expression using immunohistochemistry.
121	Was MYB translocation analysis performed?	☐ Yes ☐ No ☐ Unknown	6788037	Indicate whether an analysis for translocation in the MYB gene was performed. ***Note: If MYB translocation analysis was performed, proceed to Question 122, otherwise, skip to Question 124.***
122	Was a MYB translocation identified?	☐ Yes ☐ No	6788043	Indicate whether a MYB chromosomal translocation was identified. ***Note: If a MYB translocation was identified, proceed to Question 123, otherwise, skip to Question 124.***
123	If translocation identified with MYB, which one?	☐ MYB-NFIB ☐ Other translocation (specify)	6788049	Select the translocation identified with the MYB gene. ***Note: If the MYB translocation is not listed, proceed to Question 123a, otherwise, skip to Question 124.***
123a	Specify other MYB translocation	_____	6788054	If not included in the previous list, provide the translocation identified with the MYB gene.
Salivary Duct Carcinoma-specific Questions				
124	Was HER2 IHC performed?	☐ Yes ☐ No ☐ Unknown	6063454	Indicate whether HER2 expression was assessed by immunohisto-chemistry (IHC). ***Note: If HER2 IHC was performed, proceed to Question 125, otherwise, skip to Question 126.***
125	HER2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	2957563	Indicate the expression of HER2 as assessed by immunohistochemistry (IHC).
126	Was HER2 FISH/CISH performed?	☐ Yes ☐ No ☐ Unknown	6063447	Indicate whether HER2 was assessed by fluorescence in situ hybridization (FISH) or chromogenic in situ hybridization (CISH). ***Note: If HER2 FISH/CISH was performed, proceed to Question 127, otherwise, skip to Question 132.***
127	HER2 status by FISH/CISH	☐ Amplified ☐ Equivocal ☐ Not amplified	2854089	Select the HER2 status as assessed by FISH/CISH. ***Note: If HER2 is amplified, proceed to Question 128, otherwise, skip to Question 132.***
128	HER2 copy number	_____	3133738	If HER2 copy number testing was performed, provide the average number of HER2 fluorescence in situ hybridization (FISH) signals for the patient's primary tumor.
129	Centromere 17 copy number	_____	3104295	If Centromere 17 copy number testing was performed, provide the average number of Centromere 17 fluorescence in situ hybridization (FISH) signals for the patient's primary tumor.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
130	Number of cells counted for HER2 and centromere 17 copy numbers	_____	3087902	Provide the total number of cells counted to assess HER2 and Centromere 17 copy numbers.
131	HER2/neu chromosome 17 signal ratio	_____	2497552	If HER2 and Centromere 17 copy number analyses were performed by FISH, provide the ratio of the outcomes of these tests.
132	Was Androgen Receptor IHC performed?	☐ Yes ☐ No ☐ Unknown	6788027	Indicate whether Androgen Receptor expression was assessed by immunohistochemistry (IHC). ***Note: If androgen receptor IHC was performed, proceed to Question 133, otherwise, skip to Question 134.***
133	Androgen Receptor expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6788031	Indicate the expression of Androgen Receptor as assessed by immunohistochemistry (IHC).
Primary Tumor Sample Information				
134	Are you submitting a primary tumor tissue sample for this case?	☐ Yes ☐ No		***If yes, proceed to question 135.*** ***If submitting a metastatic/recurrent tumor biospecimen, proceed to Question 167.***
135	Primary tumor biospecimen ordinal	_____	6584265	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number should be "1".***
136	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
137	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
138	Sample represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this primary tumor specimen represent the PRIMARY DIAGNOSIS for this Case ID3? ***Note: If no, continue to Question 139, otherwise, skip to Question 140.***
139	Specify the ICD-10 code	_____	3226287	Provide the ICD-10 code for the primary tumor used to generate the model submitted to HCMI.
140	Tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the tumor tissue sample collected for molecular characterization.
141	Anatomic site from which the tumor was obtained: Lip and oral cavity	☐ External upper lip ☐ External lower lip ☐ Mucosa of upper lip ☐ Mucosa of lower lip ☐ Commissure of lip ☐ Lateral border of tongue ☐ Ventral surface of tongue ☐ Dorsal surface of tongue ☐ Anterior two-thirds of tongue ☐ Upper gingiva ☐ Lower gingiva ☐ Anterior floor of mouth	4214629	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI. ***Note: If the tissue or organ not listed, proceed to Question 141a. Otherwise, skip to Question 142.***



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		☐ Floor of mouth ☐ Hard palate ☐ Buccal mucosa ☐ Vestibule of mouth, maxillary ☐ Vestibule of mouth, mandibular ☐ Alveolar process, maxillary ☐ Alveolar process, mandibular ☐ Retromolar area ☐ Mandible ☐ Maxilla ☐ Other (specify)		
141a	Other anatomic site from which the tumor was obtained: Lip and oral cavity	_____	5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.
142	Anatomic site from which the tumor was obtained: Pharynx	☐ Palatine tonsil ☐ Base of tongue, including lingual tonsil ☐ Soft palate ☐ Uvula ☐ Pharyngeal wall (posterior) ☐ Nasopharyngeal tonsils (adenoids) ☐ Piriform sinus ☐ Postcricoid ☐ Pharyngeal wall (posterior and/or lateral) ☐ Other (specify)	4214629	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI. ***Note: If the tissue or organ not listed, proceed to Question 142a. Otherwise, skip to Question 143.***
142a	Other anatomic site from which the tumor was obtained: Pharynx	_____	5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.
143	Anatomic site from which the tumor was obtained: Larynx	☐ Epiglottis, lingual aspect ☐ Epiglottis, laryngeal aspect ☐ Aryepiglottic folds ☐ Arytenoid(s) ☐ False vocal cord ☐ Larynx ventricle ☐ True vocal cord ☐ Anterior commissure of glottis ☐ Posterior commissure of glottis ☐ Glottis, with subglottic extension ☐ Subglottis ☐ Other (specify)	4214629	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI. ***Note: If the tissue or organ not listed, proceed to Question 143a. Otherwise, skip to Question 144.***
143a	Other anatomic site from which the tumor was obtained: Larynx	_____	5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.
144	Anatomic site from which the tumor was obtained: Paranasal sinuses and nasal cavity	☐ Nasal septum ☐ Nasal floor ☐ Nasal lateral wall ☐ Nasal vestibule ☐ Nasal cavity, NOS ☐ Paranasal sinus(es), maxillary ☐ Paranasal sinus(es), ethmoid ☐ Paranasal sinus(es), frontal ☐ Paranasal sinus(es), sphenoid ☐ Other (specify)	4214629	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI. ***Note: If the tissue or organ not listed, proceed to Question 144a. Otherwise, skip to Question 145.***
144a	Other anatomic site from which the tumor was obtained: Paranasal sinuses and nasal cavity	_____	5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
145	Anatomic site from which the tumor was obtained: Salivary glands	☐ Parotid gland, superficial lobe ☐ Parotid gland, deep lobe ☐ Parotid gland, total ☐ Submandibular gland ☐ Sublingual gland ☐ Minor gland(s) ☐ Other (specify)	4214629	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI. ***Note: If the tissue or organ not listed, proceed to Question 145a. Otherwise, skip to Question 146.***
145a	Other anatomic site from which the tumor was obtained: Salivary glands	_____	5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.
146	Method of cancer sample procurement	☐ Buccal mucosal resection ☐ Core needle biopsy ☐ Endolaryngeal excision ☐ Excision ☐ Fine needle aspirate ☐ Glossectomy ☐ Incisional biopsy ☐ Laryngopharyngectomy ☐ Mandibulectomy ☐ Maxillectomy ☐ Neck (lymph node) dissection ☐ Palatectomy ☐ Parotidectomy, deep ☐ Parotidectomy, not specified ☐ Parotidectomy, superficial ☐ Parotidectomy, total ☐ Partial laryngectomy ☐ Partial maxillectomy ☐ Radical maxillectomy ☐ Resection, sublingual gland ☐ Resection, submandibular gland ☐ Supracricoid laryngectomy ☐ Supraglottic laryngectomy ☐ Tonsillectomy ☐ Total laryngectomy ☐ Transoral laser excision (glottis) ☐ Vertical hemilaryngectomy ☐ Other (specify)	3103514	Provide the procedure performed to obtain the primary tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 146a, otherwise, skip to Question 147.***
146a	Specify the other method of tumor sample procurement	_____	2006730	Specify the procedure performed to obtain the primary tumor tissue, if not included in the previous list.
147	Number of days from index date to date of tumor sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the tumor tissue submitted for HCMI.
148	Tumor tissue type	☐ Primary ☐ Additional Primary ☐ NOS	3288124	Provide the primary tumor tissue type for this sample.
Primary Tumor Model Information				
149	Primary model biospecimen ordinal	_____	6594596	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number is expected to be "1".***
150	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
151	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
152	Model represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this MODEL represent the PRIMARY DIAGNOSIS for this Case ID3?
153	Model's primary tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the PRIMARY TUMOR TISSUE from which this model is derived.
154	Model's primary tumor biospecimen ordinal	_____	6584265	Enter the biospecimen ordinal of the PRIMARY TUMOR TISSUE from which this model is derived.
Treatment Information				
155	History of neoadjuvant treatment	☐ No ☐ Yes; radiation prior to resection ☐ Yes; pharmaceutical treatment prior to resection ☐ Yes; both radiation and pharmaceutical treatment prior to resection ☐ Unknown	3382737	Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment. ***Note: Pharmaceutical therapy is addressed in Questions 156-164. Radiation therapy is addressed in Questions 165-166.***
156	Neoadjuvant chemotherapy type	☐ Cytotoxic chemotherapy ☐ Hormonal ☐ Immunotherapy (cellular and immune checkpoint) ☐ Targeted therapy (small molecule inhibitors and targeted antibodies) ☐ Not applicable	5832928	Select all neoadjuvant chemotherapy types that were administered to the patient. ***Note: Cytotoxic chemotherapy is addressed in Questions 157-158. Hormone therapy is addressed in Questions 159-160. Immunotherapy is addressed in Questions 161-162. Targeted therapy is addressed in Questions 163-164.***
157	Neoadjuvant chemotherapeutic regimen	☐ Cisplatin ☐ Carboplatin and Paclitaxel ☐ Docetaxel, Carboplatin, and Fluorouracil ☐ Carboplatin, Paclitaxel, and Cetuximab ☐ Carboplatin (Cisplatin), Fluorouracil, and Pembrolizumab ☐ Other (specify)	2853313	Select all chemotherapeutics used for neoadjuvant therapy. ***Note: If neoadjuvant chemotherapy was not given, skip to Question 159. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 157a, otherwise, skip to Question 158.***
157a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapies administered.
158	Days to neoadjuvant chemotherapy treatment from index date	_____	5102411	Provide the number of days from index date to the date of treatment with neoadjuvant chemotherapy.
159	Hormone therapy	☐ Herceptin ☐ Androgen deprivation (specify) ☐ Other (specify)	2582817	Select the hormone therapy administered to the patient. ***Note: If hormone therapy was not given, skip to Question 161. If the androgen deprivation was given, proceed to Question 159a. If the hormone therapy is not listed, proceed to Question 159b, otherwise, skip to Question 160.***
159a	Specify the androgen deprivation therapy	_____	6942918	Specify the androgen deprivation therapies administered.
159b	Other hormone therapy	_____	2405358	If the hormone therapy is not included in the provided list, specify hormone therapy.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
160	Days to hormone therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with hormone therapy.
161	Immunotherapy	☐ Pembrolizumab ☐ Nivolumab ☐ Cemiplimab ☐ Durvalumab ☐ Ipilimumab ☐ Tremelimumab ☐ Pembrolizumab plus Ipilimumab ☐ Durvalumab plus Tremelimumab ☐ Other (specify)	6788001	Select the immunotherapy administered to the patient. ***Note: If immunotherapy was not administered, skip to Question 163. If the immunotherapy is not listed, proceed to Question 161a, otherwise, skip to Question 162.***
161a	Specify other immunotherapy	_____	2953828	Provide the name of the immunotherapy administered to the patient.
162	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
163	Targeted Therapy	☐ Cetuximab ☐ Cetuximab, Carboplatin (Cisplatin), Fluorouracil ☐ Cetuximab, Carboplatin, and Paclitaxel ☐ Bevacizumab ☐ Panitumumab ☐ Lenvatinib ☐ Afatinib ☐ Other (specify)	6788000	Select the targeted therapy administered to the patient. ***Note: If targeted therapy was not administered, skip to Question 165. If the targeted therapy regimen is not listed, proceed to Question 163a, otherwise, skip to Question 164.***
163a	Specify targeted therapy	_____	4308476	Provide the name of the targeted therapy administered to the patient.
164	Days to targeted therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with targeted therapy.
165	Radiation therapy administered type	☐ 2D conventional ☐ 3D conformal ☐ Brachytherapy HDR ☐ Brachytherapy LDR ☐ IMRT ☐ Proton Beam ☐ Stereotactic Body RT ☐ Stereotactic Radiosurgery ☐ WBRT ☐ Other (specify) ☐ Unspecified ☐ Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. ***Note: If radiation therapy was not administered, proceed to Question 167. If the radiation therapy is not listed, proceed to Question 165a, otherwise, skip to Question 166.***
165a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
166	Days to radiation treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with radiation therapy.
Metastatic/Recurrent Tumor Biospecimen Information				
167	Are you submitting a metastatic/recurrent tumor tissue sample?	☐ Yes ☐ No		Indicate whether a metastatic/recurrent tumor biospecimen was collected for this ID3 case. ***Note: If yes, proceed to Question 168. If submitting an OTHER tissue sample, proceed to Question 256.***
168	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1", the second should be number "2", etc.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
169	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
170	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
171	Head and neck cancer region	☐ Lip and oral cavity ☐ Pharynx ☐ Larynx ☐ Paranasal sinuses and nasal cavity ☐ Salivary glands	2179718	Select the anatomic site of origin for the head and neck cancer in the patient.
172	Metastatic/recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
173	Number of days from index date to date of diagnosis of metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic/recurrent disease.
174	Method of metastatic/ recurrent cancer sample procurement	☐ Buccal mucosal resection ☐ Endolaryngeal excision ☐ Excision ☐ Glossectomy ☐ Incisional biopsy ☐ Laryngopharyngectomy ☐ Mandibulectomy ☐ Maxillectomy ☐ Metastasectomy ☐ Neck (lymph node) dissection ☐ Palatectomy ☐ Parotidectomy, deep ☐ Parotidectomy, not specified ☐ Parotidectomy, superficial ☐ Parotidectomy, total ☐ Partial laryngectomy ☐ Partial maxillectomy ☐ Radical maxillectomy ☐ Resection, sublingual gland ☐ Resection, submandibular gland ☐ Supracricoid laryngectomy ☐ Supraglottic laryngectomy ☐ Tonsillectomy ☐ Total laryngectomy ☐ Transoral laser excision (glottis) ☐ Vertical hemilaryngectomy ☐ Other Method (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 174a, otherwise, skip to Question 175.***
174a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
175	Number of days from index date to date of metastatic/recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
176	Metastatic/recurrent site	☐ Alveolar process, mandibular ☐ Alveolar process, maxillary ☐ Anterior commissure of glottis ☐ Anterior floor of mouth ☐ Anterior two-thirds of tongue ☐ Aryepiglottic folds ☐ Arytenoid(s) ☐ Base of tongue, including lingual tonsil ☐ Bone ☐ Bone marrow ☐ Buccal mucosa ☐ Commissure of lip ☐ Dorsal surface of tongue ☐ Epiglottis, laryngeal aspect ☐ Epiglottis, lingual aspect ☐ External lower lip ☐ External upper lip ☐ False vocal cord ☐ Floor of mouth ☐ Glottis, with subglottic extension ☐ Hard palate ☐ Larynx ventricle ☐ Lateral border of tongue ☐ Liver ☐ Lower gingiva ☐ Lung ☐ Lymph node(s), non-regional ☐ Lymph node(s), regional ☐ Mandible ☐ Maxilla ☐ Mediastinum ☐ Minor gland(s) ☐ Mucosa of lower lip ☐ Mucosa of upper lip ☐ Nasal cavity, NOS ☐ Nasal floor ☐ Nasal lateral wall ☐ Nasal septum ☐ Nasal vestibule ☐ Nasopharyngeal tonsils (adenoids) ☐ Palatine tonsil ☐ Paranasal sinus(es), ethmoid ☐ Paranasal sinus(es), frontal ☐ Paranasal sinus(es), maxillary ☐ Paranasal sinus(es), sphenoid ☐ Parotid gland, deep lobe ☐ Parotid gland, superficial lobe ☐ Parotid gland, total ☐ Pharyngeal wall (posterior and/or lateral) ☐ Pharyngeal wall (posterior) ☐ Piriform sinus ☐ Postcricoid ☐ Posterior commissure of glottis ☐ Retromolar area ☐ Skin ☐ Soft palate ☐ Subglottis ☐ Sublingual gland ☐ Submandibular gland	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 176a, otherwise, skip to Question 177.***



Enrollment: Head and Neck

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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		☐ True vocal cord ☐ Upper gingiva ☐ Uvula ☐ Ventral surface of tongue ☐ Vestibule of mouth, mandibular ☐ Vestibule of mouth, maxillary ☐ Other (specify)		
176a	Other metastatic/ recurrent site	_____	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
177	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
178	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
179	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
180	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
181	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
182	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
183	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
184	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
Prognostic/Predictive/Lifestyle Features for Metastatic/Recurrent Tumor Prognosis or Responsiveness to Treatment				
185	Tumor laterality	☐ Right ☐ Left ☐ Bilateral ☐ Midline ☐ Not specified ☐ Not a paired site	827	For a tumor in a paired organ, designate the side of the body on which the tumor or cancer developed.
186	Lymphovascular invasion present?	☐ Yes ☐ No ☐ Indeterminate ☐ Unknown	64727	Indicate whether large vessel (vascular) invasion or small, thin-walled (lymphatic) invasion was detected in the primary tumor.
187	Perineural invasion present?	☐ Yes ☐ No ☐ Unknown	64181	Indicate whether perineural invasion or infiltration of tumor or cancer is present.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
188	Number of positive lymph nodes	_____	89	Provide the number of lymph nodes with disease involvement.
189	Number of lymph nodes tested	_____	3	Provide the total number of lymph nodes tested for the presence of cancer cells.
190	Extranodal extension	☐ Present ☐ Absent ☐ Unknown	65043	Indicate whether extranodal extension of the cancer is present.
191	Was p16 IHC performed?	☐ Yes ☐ No ☐ Unknown	6690713	Indicate whether or not immunohistochemical analysis for a p16/CDKN2A mutation was performed. ***Note: If p16 IHC was performed, proceed to Question 192, otherwise, skip to Question 193.***
192	p16 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6690724	Indicate the status of the p16/CDKN2A protein expression using immunohistochemistry.
Larynx Cancer-specific Questions				
193	Transglottic extension	☐ Present ☐ Not identified	6788023	Indicate whether a transglottic extension of the patient's laryngeal tumor was present.
Paranasal Sinuses and Nasal Cavity Cancer-specific Questions				
194	Was NUT IHC performed?	☐ Yes ☐ No ☐ Unknown	6788024	Indicate whether NUTM1 protein expression by immunohisto-chemistry (IHC) analysis was performed. ***Note: If NUT IHC was performed, proceed to Question 195, otherwise, skip to Question 196.***
195	NUT expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6788028	Indicate the status of the NUTM1 protein expression using immunohistochemistry.
196	Was NUT translocation analysis performed?	☐ Yes ☐ No ☐ Unknown	6788032	Indicate whether an analysis for translocation in the NUTM1 gene was performed. ***Note: If NUT translocation analysis was performed, proceed to Question 197, otherwise, skip to Question 199.***
197	Was a NUT translocation identified?	☐ Yes ☐ No	6788038	Indicate whether a NUTM1 chromosomal translocation was identified. ***Note: If a NUT translocation was identified, proceed to Question 198, otherwise, skip to Question 199.***
198	If translocation identified with NUT, which one?	☐ NUT-BRD4 ☐ Other translocation (specify)	6788044	Select the translocation identified with the NUTM1 gene. ***Note: If the NUT translocation is not listed, proceed to Question 198a, otherwise, skip to Question 199.***
198a	Specify other NUT translocation	_____	6788055	If not included in the previous list, provide the translocation identified with the NUTM1 gene.
199	Was INI-1 IHC performed?	☐ Yes ☐ No ☐ Unknown	6788025	Indicate whether INI-1 (SMARCB1) protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If INI-1 IHC was performed, proceed to Question 200, otherwise, skip to Question 201.***



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
200	INI-1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6788029	Indicate the status of the INI-1 (SMARCB1) protein expression using immunohistochemistry.
201	Was PAX3 translocation analysis performed?	☐ Yes ☐ No ☐ Unknown	6788033	Indicate whether an analysis for translocation in the PAX3 gene was performed. ***Note: If PAX3 translocation analysis was performed, proceed to Question 202, otherwise skip to question 204.***
202	Was a PAX3 translocation identified?	☐ Yes ☐ No	6788039	Indicate whether a PAX3 chromosomal translocation was identified. ***Note: If a PAX3 translocation was identified, proceed to Question 203, otherwise, skip to Question 204.***
203	If translocation identified with PAX3, which one?	☐ PAX3-MAML3 ☐ Other translocation (specify)	6788045	Select the translocation identified with the PAX3 gene. ***Note: If the PAX3 translocation is not listed, proceed to Question 203a, otherwise skip to Question 204.***
203a	Specify other PAX3 translocation	_____	6788050	If not included in the previous list, provide the translocation identified with the PAX3 gene.
204	Was EWSR1 translocation analysis performed?	☐ Yes ☐ No ☐ Unknown	6788034	Indicate whether an analysis for translocation in the EWSR1 gene was performed. ***Note: If EWSR1 translocation analysis was performed, proceed to Question 205, otherwise, skip to Question 207.***
205	Was an EWSR1 translocation identified?	☐ Yes ☐ No	6788040	Indicate whether an EWSR1 chromosomal translocation was identified. ***Note: If an EWSR1 translocation was identified, proceed to Question 206, otherwise, skip to Question 207.***
206	If translocation identified with EWSR1, which one?	☐ EWSR1-ATF1 ☐ Other translocation	6788046	Select the translocation identified with the EWSR1 gene. ***Note: If the EWSR1 translocation is not listed, proceed to Question 206a, otherwise skip to Question 207.***
206a	Specify other EWSR1 translocation	_____	6788051	If not included in the previous list, provide the translocation identified with the EWSR1 gene.
207	Was ETV6 translocation analysis performed?	☐ Yes ☐ No ☐ Unknown	6788035	Indicate whether an analysis for translocation in the ETV6 gene was performed. ***Note: If ETV6 translocation analysis was performed, proceed to Question 208, otherwise, skip to Question 210.***
208	Was an ETV6 translocation identified?	☐ Yes ☐ No	6788041	Indicate whether an ETV6 chromosomal translocation was identified. ***Note: If an ETV6 translocation was identified, proceed to Question 209, otherwise, skip to Question 210.***
209	If translocation identified with ETV6, which one?	☐ ETV6-NTRK3 ☐ Other translocation (specify)	6788047	Select the translocation identified with the ETV6 gene. ***Note: If the ETV6 translocation is not listed, proceed to Question 209a, otherwise skip to Question 210.***



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
209a	Specify other ETV6 translocation	_____	6788052	If not included in the previous list, provide the translocation identified with the ETV6 gene.
210	Was MAML2 translocation analysis performed?	☐ Yes ☐ No ☐ Unknown	6788036	Indicate whether an analysis for translocation in the MAML2 gene was performed. ***Note: If MAML2 translocation analysis was performed, proceed to Question 211, otherwise, skip to Question 213.***
211	Was a MAML2 translocation identified?	☐ Yes ☐ No	6788042	Indicate whether a MAML2 chromosomal translocation was identified. ***Note: If a MAML2 translocation was identified, proceed to Question 212, otherwise, skip to Question 213.***
212	If translocation identified with MAML2, which one?	☐ MAML2-CRTC1 ☐ MAML2-CRTC3 ☐ Other translocation (specify)	6788048	Select the translocation identified with the MAML2 gene. ***Note: If the MAML2 translocation is not listed, proceed to Question 212a, otherwise, skip to Question 213.***
212a	Specify other MAML2 translocation	_____	6788053	If not included in the previous list, provide the translocation identified with the MAML2 gene.
213	Was MYB IHC performed?	☐ Yes ☐ No ☐ Unknown	6788026	Indicate whether MYB protein expression by immunohisto-chemistry (IHC) analysis was performed. ***Note: If MYB IHC was performed, proceed to Question 214, otherwise, skip to Question 215.***
214	MYB expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6788030	Indicate the status of the MYB protein expression using immunohistochemistry.
215	Was MYB translocation analysis performed?	☐ Yes ☐ No ☐ Unknown	6788037	Indicate whether an analysis for translocation in the MYB gene was performed. ***Note: If MYB translocation analysis was performed, proceed to Question 216, otherwise, skip to Question 218.***
216	Was a MYB translocation identified?	☐ Yes ☐ No	6788043	Indicate whether a MYB chromosomal translocation was identified. ***Note: If a MYB translocation was identified, proceed to Question 217, otherwise, skip to Question 218.***
217	If translocation identified with MYB, which one?	☐ MYB-NFIB ☐ Other translocation (specify)	6788049	Select the translocation identified with the MYB gene. ***Note: If the MYB translocation is not listed, proceed to Question 217a, otherwise, skip to Question 218.***
217a	Specify other MYB translocation	_____	6788054	If not included in the previous list, provide the translocation identified with the MYB gene.
218	Was HER2 IHC performed?	☐ Yes ☐ No ☐ Unknown	6063454	Indicate whether HER2 expression was assessed by immunohisto-chemistry (IHC). ***Note: If HER2 IHC was performed, proceed to Question 219, otherwise, skip to Question 220.***
219	HER2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	2957563	Indicate the expression of HER2 as assessed by immunohistochemistry (IHC).



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
220	Was HER2 FISH/CISH performed?	☐ Yes ☐ No ☐ Unknown	6063447	Indicate whether HER2 was assessed by fluorescence in situ hybridization (FISH) or chromogenic in situ hybridization (CISH). ***Note: If HER2 FISH/CISH was performed, proceed to Question 221, otherwise, skip to Question 226.***
221	HER2 status by FISH/CISH	☐ Amplified ☐ Not amplified ☐ Equivocal	2854089	Select the HER2 status as assessed by FISH/CISH.
222	HER2 copy number	_____	3133738	If HER2 copy number testing was performed, provide the average number of HER2 fluorescence in situ hybridization (FISH) signals for the patient's primary tumor.
223	Centromere 17 copy number	_____	3104295	If Centromere 17 copy number testing was performed, provide the average number of Centromere 17 fluorescence in situ hybridization (FISH) signals for the patient's primary tumor.
224	Number of cells counted for HER2 and centromere 17 copy numbers	_____	3087902	Provide the total number of cells counted to assess HER2 and Centromere 17 copy numbers.
225	HER2/neu chromosome 17 signal ratio	_____	2497552	If HER2 and Centromere 17 copy number analyses were performed by FISH, provide the ratio of the outcomes of these tests.
226	Was Androgen Receptor IHC performed?	☐ Yes ☐ No ☐ Unknown	6788027	Indicate whether Androgen Receptor expression was assessed by immunohistochemistry (IHC). ***Note: If androgen receptor IHC was performed, proceed to Question 227, otherwise, skip to Question 228.***
227	Androgen Receptor expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6788031	Indicate the expression of Androgen Receptor as assessed by immunohistochemistry (IHC).
Additional Metastatic/Recurrent Tumor Biospecimen Information (if applicable)				
228	Are you submitting an additional metastatic/ recurrent tumor tissue sample?	☐ Yes ☐ No		A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen. ***Note: If yes, proceed to Question 229, otherwise, skip to Question 246.***
229	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. The first biospecimen should be number "1," the second should be number "2," etc.
230	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
231	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
232	Head and neck cancer region	☐ Lip and oral cavity ☐ Pharynx ☐ Larynx ☐ Paranasal sinuses and nasal cavity ☐ Salivary glands	2179718	Select the anatomic site of origin for the head and neck cancer in the patient.
233	Metastatic/recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
234	Number of days from index date to date of diagnosis of additional metastasis/recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of additional metastatic/recurrent disease.
235	Method of metastatic/ recurrent cancer sample procurement	☐ Buccal mucosal resection ☐ Endolaryngeal excision ☐ Excision ☐ Glossectomy ☐ Incisional biopsy ☐ Laryngopharyngectomy ☐ Mandibulectomy ☐ Maxillectomy ☐ Metastasectomy ☐ Neck (lymph node) dissection ☐ Palatectomy ☐ Parotidectomy, deep ☐ Parotidectomy, not specified ☐ Parotidectomy, superficial ☐ Parotidectomy, total ☐ Partial laryngectomy ☐ Partial maxillectomy ☐ Radical maxillectomy ☐ Resection, sublingual gland ☐ Resection, submandibular gland ☐ Supracricoid laryngectomy ☐ Supraglottic laryngectomy ☐ Tonsillectomy ☐ Total laryngectomy ☐ Transoral laser excision (glottis) ☐ Vertical hemilaryngectomy ☐ Other Method (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 235a, otherwise, skip to Question 236.***
235a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
236	Number of days from index date to date of metastatic/recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
237	Metastatic/recurrent site	☐ Alveolar process, mandibular ☐ Alveolar process, maxillary ☐ Anterior commissure of glottis ☐ Anterior floor of mouth ☐ Anterior two-thirds of tongue ☐ Aryepiglottic folds ☐ Arytenoid(s) ☐ Base of tongue, including lingual tonsil ☐ Bone ☐ Bone marrow ☐ Buccal mucosa ☐ Commissure of lip ☐ Dorsal surface of tongue ☐ Epiglottis, laryngeal aspect ☐ Epiglottis, lingual aspect ☐ External lower lip ☐ External upper lip ☐ False vocal cord ☐ Floor of mouth ☐ Glottis, with subglottic extension ☐ Hard palate ☐ Larynx ventricle ☐ Lateral border of tongue ☐ Liver ☐ Lower gingiva ☐ Lung ☐ Lymph node(s), non-regional ☐ Lymph node(s), regional ☐ Mandible ☐ Maxilla ☐ Mediastinum ☐ Minor gland(s) ☐ Mucosa of lower lip ☐ Mucosa of upper lip ☐ Nasal cavity, NOS ☐ Nasal floor ☐ Nasal lateral wall ☐ Nasal septum ☐ Nasal vestibule ☐ Nasopharyngeal tonsils (adenoids) ☐ Palatine tonsil ☐ Paranasal sinus(es), ethmoid ☐ Paranasal sinus(es), frontal ☐ Paranasal sinus(es), maxillary ☐ Paranasal sinus(es), sphenoid ☐ Parotid gland, deep lobe ☐ Parotid gland, superficial lobe ☐ Parotid gland, total ☐ Pharyngeal wall (posterior and/or lateral) ☐ Pharyngeal wall (posterior) ☐ Piriform sinus ☐ Postcricoid ☐ Posterior commissure of glottis ☐ Retromolar area ☐ Skin ☐ Soft palate ☐ Subglottis ☐ Sublingual gland ☐ Submandibular gland	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 237a, otherwise, skip to Question 238.***



Enrollment: Head and Neck

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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		☐ True vocal cord ☐ Upper gingiva ☐ Uvula ☐ Ventral surface of tongue ☐ Vestibule of mouth, mandibular ☐ Vestibule of mouth, maxillary ☐ Other (specify)		
237a	Other metastatic/ recurrent site	_____	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
238	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
239	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
240	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
241	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
242	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
243	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
244	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
245	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
Additional Metastatic/Recurrent Tumor Prognostic/Predictive/Lifestyle Features for Additional Metastatic/Recurrent Tumor Prognosis or Responsiveness to Treatment (Note: Questions 185-227 may be repeated to capture clinical molecular characterization information for additional metastatic/recurrent biospecimens.)				
Metastatic/Recurrent Tumor Model Information				
246	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
247	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
248	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
249	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
250	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Additional Metastatic/Recurrent Biospecimen Tumor Model Information (if applicable)				
251	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
252	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
253	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
254	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
255	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Other Biospecimen Information				
256	Are you submitting an OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an OTHER tissue sample (e.g. pre-malignant, non-malignant, or dysplastic tissue, etc.) was collected for HCMI for this case. ***Note: If yes, proceed to Question 257.***
257	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
258	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
259	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
260	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
261	Other method of cancer sample procurement	☐ Buccal mucosal resection ☐ Core needle biopsy ☐ Endolaryngeal excision ☐ Excision ☐ Fine needle aspirate ☐ Glossectomy ☐ Incisional biopsy ☐ Laryngopharyngectomy ☐ Mandibulectomy ☐ Maxillectomy ☐ Neck (lymph node) dissection ☐ Palatectomy ☐ Parotidectomy, deep ☐ Parotidectomy, not specified ☐ Parotidectomy, superficial ☐ Parotidectomy, total ☐ Partial laryngectomy ☐ Partial maxillectomy ☐ Radical maxillectomy ☐ Resection, sublingual gland ☐ Resection, submandibular gland ☐ Supracricoid laryngectomy ☐ Supraglottic laryngectomy ☐ Tonsillectomy ☐ Total laryngectomy ☐ Transoral laser excision (glottis) ☐ Vertical hemilaryngectomy ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 261a, otherwise, skip to Question 262.***
261a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
262	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
263	Tissue type	☐ Pre-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 263a, otherwise, skip to Question 264.***
263a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
264	Anatomic site of OTHER tissue	☐ Alveolar process, mandibular ☐ Alveolar process, maxillary ☐ Anterior commissure ☐ Anterior floor of mouth ☐ Anterior two-thirds of tongue ☐ Aryepiglottic folds ☐ Arytenoid(s) ☐ Base of tongue, including lingual tonsil ☐ Buccal mucosa ☐ Commissure of lip ☐ Dorsal surface of tongue ☐ Epiglottis, laryngeal aspect ☐ Epiglottis, lingual aspect ☐ External lower lip ☐ External upper lip ☐ False vocal cord	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 264a, otherwise, skip to Question 265.***



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

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		☐ Floor of mouth ☐ Glottis, with subglottic extension ☐ Hard palate ☐ Larynx ventricle ☐ Lateral border of tongue ☐ Lower gingiva ☐ Mandible ☐ Maxilla ☐ Mucosa of lower lip ☐ Mucosa of upper lip ☐ Nasal cavity, NOS ☐ Nasal floor ☐ Nasal lateral wall ☐ Nasal septum ☐ Nasal vestibule ☐ Nasopharyngeal tonsils (adenoids) ☐ Palatine tonsil ☐ Paranasal sinus(es), ethmoid ☐ Paranasal sinus(es), frontal ☐ Paranasal sinus(es), maxillary ☐ Paranasal sinus(es), sphenoid ☐ Parotid gland, deep lobe ☐ Parotid gland, superficial lobe ☐ Parotid gland, total ☐ Pharyngeal wall (posterior and/or lateral) ☐ Pharyngeal wall (posterior) ☐ Piriform sinus ☐ Postcricoid ☐ Posterior commissure ☐ Retromolar area ☐ Soft palate ☐ Subglottis ☐ Sublingual gland ☐ Submandibular gland ☐ True vocal cord ☐ Upper gingiva ☐ Uvula ☐ Ventral surface of tongue ☐ Vestibule of mouth, mandibular ☐ Vestibule of mouth, maxillary ☐ Other (specify)		
264a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.
265	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
266	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Additional OTHER biospecimen Information (if applicable)				
267	Are you submitting an additional OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an additional OTHER tissue sample (pre-malignant, non-malignant, or dysplastic tissue, etc.) is being submitted for HCMI for this case. ***Note: If yes, proceed to Question 268, otherwise, skip to Question 278.***



Enrollment: Head and Neck

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
268	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
269	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
270	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
271	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
272	Other method of cancer sample procurement	☐ Buccal mucosal resection ☐ Core needle biopsy ☐ Endolaryngeal excision ☐ Excision ☐ Fine needle aspirate ☐ Glossectomy ☐ Incisional biopsy ☐ Laryngopharyngectomy ☐ Mandibulectomy ☐ Maxillectomy ☐ Neck (lymph node) dissection ☐ Palatectomy ☐ Parotidectomy, deep ☐ Parotidectomy, not specified ☐ Parotidectomy, superficial ☐ Parotidectomy, total ☐ Partial laryngectomy ☐ Partial maxillectomy ☐ Radical maxillectomy ☐ Resection, sublingual gland ☐ Resection, submandibular gland ☐ Supracricoid laryngectomy ☐ Supraglottic laryngectomy ☐ Tonsillectomy ☐ Total laryngectomy ☐ Transoral laser excision (glottis) ☐ Vertical hemilaryngectomy ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 272a, otherwise, skip to Question 273.***
272a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
273	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
274	Tissue type	☐ Pre-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 274a, otherwise, skip to Question 275.***
274a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.



Enrollment: Head and Neck

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
275	Anatomic site of OTHER tissue	☐ Alveolar process, mandibular ☐ Alveolar process, maxillary ☐ Anterior commissure ☐ Anterior floor of mouth ☐ Anterior two-thirds of tongue ☐ Aryepiglottic folds ☐ Arytenoid(s) ☐ Base of tongue, including lingual tonsil ☐ Buccal mucosa ☐ Commissure of lip ☐ Dorsal surface of tongue ☐ Epiglottis, laryngeal aspect ☐ Epiglottis, lingual aspect ☐ External lower lip ☐ External upper lip ☐ False vocal cord ☐ Floor of mouth ☐ Glottis, with subglottic extension ☐ Hard palate ☐ Larynx ventricle ☐ Lateral border of tongue ☐ Lower gingiva ☐ Mandible ☐ Maxilla ☐ Mucosa of lower lip ☐ Mucosa of upper lip ☐ Nasal cavity, NOS ☐ Nasal floor ☐ Nasal lateral wall ☐ Nasal septum ☐ Nasal vestibule ☐ Nasopharyngeal tonsils (adenoids) ☐ Palatine tonsil ☐ Paranasal sinus(es), ethmoid ☐ Paranasal sinus(es), frontal ☐ Paranasal sinus(es), maxillary ☐ Paranasal sinus(es), sphenoid ☐ Parotid gland, deep lobe ☐ Parotid gland, superficial lobe ☐ Parotid gland, total ☐ Pharyngeal wall (posterior and/or lateral) ☐ Pharyngeal wall (posterior) ☐ Piriform sinus ☐ Postcricoid ☐ Posterior commissure ☐ Retromolar area ☐ Soft palate ☐ Subglottis ☐ Sublingual gland ☐ Submandibular gland ☐ True vocal cord ☐ Upper gingiva ☐ Uvula ☐ Ventral surface of tongue ☐ Vestibule of mouth, mandibular ☐ Vestibule of mouth, maxillary ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 275a, otherwise, skip to Question 276.***
275a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.



Enrollment: Head and Neck

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
276	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
277	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Other Tissue Model Information				
278	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
279	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
280	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
281	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
282	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.
Additional Other Tissue Model Information (if applicable)				
283	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
284	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
285	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
286	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
287	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.



Enrollment: Hepatocellular Carcinoma and Intrahepatic Bile Duct

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Form Notes: An Enrollment Form should be completed for each HCMI case upon qualification notice from Leidos. All information provided on this form should include activity from the Date of Initial Pathologic Diagnosis to the most recent Date of Last Contact with the patient.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	☐ Initial pathologic diagnosis ☐ Sample procurement ☐ First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.
Patient Information				
4	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.
5	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. ***Note: If the patient's age is greater than 32,872 days (90 years), please enter 32,872.***
6	Gender	☐ Male ☐ Female ☐ Unspecified	2200604	Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
7	Height	_____	649	Provide the patient's height, in centimeters.
8	Weight	_____	651	Provide the patient's weight, in kilograms.
9	Body mass index (BMI)	_____	2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
10	Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown ☐ Not reported	2192199	Provide the patient's race using the defined categories. **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 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. **Black or African American:** A person having origins in any of the black racial groups of Africa. **Native Hawaiian or other Pacific Islander:** A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island. **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.



Enrollment: Hepatocellular Carcinoma and Intrahepatic Bile Duct

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
11	Ethnicity	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Not reported	2192217	Provide the patient's ethnicity using the defined categories. **Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. **Not Hispanic or Latino:** A person not meeting the definition of Hispanic or Latino.
12	Year of birth	_____	2896954	Provide the year of the patient's birth. ***Note: If the patient was born prior to 1928, insert the date 1928.***
13	Family history of cancer	☐ Same ☐ Different ☐ None ☐ Unknown	5832923	Has a first-degree relative of the patient been diagnosed with a cancer of the same or a different type?
14	Smoking history	☐ Lifelong non-smoker (<100 cigarettes smoked in a lifetime) ☐ Current smoker (includes daily and non-daily smokers) ☐ Current reformed smoker (duration not specified) ☐ Current reformed smoker for >15 years ☐ Current reformed smoker for ≤15 years	2181650	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories.
15	Metastasis at diagnosis assessment status	☐ Metastatic ☐ Non-metastatic (confirmed) ☐ Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor. ***Note: If 'metastatic' is selected, proceed to Question 15a.***
15a	Metastatic site(s) at diagnosis	☐ Bone ☐ Brain ☐ Lung ☐ Other (specify)	3029815	Indicate the site(s) of metastasis at the time of diagnosis of the primary tumor. ***Note: If the anatomic site of tumor tissue is not listed, proceed to Question 15b, otherwise, skip to Question 16.***
15b	Specify metastatic site(s)	_____	3128033	If the site of metastasis is not included on the provided list, specify the site of metastasis.
Biospecimen Information				
16	Tissue sample type(s) collected for HCMI for this case	☐ Normal tissue ☐ Primary tumor ☐ Metastatic ☐ Recurrent ☐ Other tissue	2006911	Please select all the tissue sample types submitted for HCMI with this case.
17	Number of NORMAL tissues biospecimens collected for HCMI for this case	_____	6584256	Please provide the number of normal tissue specimens obtained for HCMI for this case. ***Note: This number is expected to be 1.***



Enrollment: Hepatocellular Carcinoma and Intrahepatic Bile Duct

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
18	Number of PRIMARY cancer tissue biospecimens collected for HCMI model development for this case	_____	6584257	Please provide the number of primary tumor specimens obtained for HCMI for this case. ***Note: A single primary tumor biospecimen obtained that is portioned for both sequencing and model generation counts as 1 single primary tumor specimen. This number is expected to be 1.***
19	Number of METASTATIC/ RECURRENT cancer tissue biospecimens collected for HCMI model development for this case	_____	6584258	Please provide the number of metastatic and/or recurrent cancer biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
20	Number of OTHER tissue biospecimens collected for HCMI model development for this case	_____	6584259	Please provide the number of pre-malignant, non-malignant, or dysplastic tissue biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
21	Total number of tissue biospecimens collected for HCMI for this case	_____	6584271	Please provide the total number of tissue biospecimens collected for HCMI for this case. ***Note: This number should be the sum of the normal, primary tumor, metastatic/recurrent tumor, and other biospecimen counts above.***
Normal Control Information				
22	Normal tissue biospecimen ordinal	_____	6584264	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
23	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
24	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.



Enrollment: Hepatocellular Carcinoma and Intrahepatic Bile Duct

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	☐ Data Entry Options	CDE ID	Instruction Text
25	Type of normal control	☐ Whole blood ☐ Buccal cells ☐ Buffy coat ☐ Lymphocytes ☐ Extracted DNA from blood ☐ Extracted DNA from saliva ☐ Extracted DNA from buccal cells ☐ Extracted DNA from normal tissue (specify) ☐ FFPE non-neoplastic tissue (specify) ☐ Non-neoplastic tissue (specify) ☐ Normal tissue from other anatomic site (specify)	3081936	Indicate the type of normal control submitted for this case. ***Note: If non-neoplastic tissue, adjacent tissue, or normal tissue from another anatomic site was submitted as the normal control, proceed to Question 25a.***
25a	Anatomic site of normal tissue	☐ Liver ☐ Pancreas ☐ Common bile duct ☐ Common hepatic duct ☐ Skin ☐ Other (specify)	4132152	If non-neoplastic tissue, adjacent tissue, or normal tissue from another anatomic site was submitted as the normal control, select the anatomic site of the normal tissue. ***Note: If the anatomic site of normal tissue is not listed, proceed to Question 25b, otherwise, skip to Question 26.***
25b	Other anatomic site of normal tissue	_____	3288189	If anatomic site of normal tissue is not in provided list, specify the site.
26	Distance from tumor to normal control tissue (if not blood)	☐ Adjacent (< or = 2cm) ☐ Distal (>2cm) ☐ Unknown ☐ Not applicable	3088708	Indicate the distance from the site of normal tumor collection to the primary tumor. ***Note: If normal tissue was not submitted, select 'Not applicable'.***
27	Normal tissue sample preservation method	☐ Cryopreserved ☐ OCT ☐ FFPE ☐ Snap frozen ☐ Frozen	5432521	Provide the method used to preserve the normal tissue sample collected for molecular characterization.
Primary Tumor Biospecimen Information				
28	ICD-10 code for primary tumor	☐ C22.0 ☐ C22.4 ☐ C22.1 ☐ C22.7 ☐ C22.2 ☐ C22.9 ☐ C22.3 ☐ Other (specify)	3226287	Provide the ICD-10 code for the primary tumor as used to generate the ID3 for this subject. ***Note: If the ICD-10 code is not listed, proceed to Question 28a, otherwise, skip to Question 29***
28a	Other ICD-10 code for primary tumor	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.
29	Tumor Morphology	☐ 4970/3 ☐ 8020/3 ☐ 8170/3 ☐ 8171/3 ☐ 8180/3 ☐ 8963/3 ☐ 8980/3 ☐ Other (specify)	3226275	Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor. ***Note: If the ICD-O-3 histology code of the primary tumor is not listed, proceed to Question 29a, otherwise, skip to Question 30.***
29a	Specify other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.



Enrollment: Hepatocellular Carcinoma and Intrahepatic Bile Duct

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
30	Tissue or organ of origin	☐ Liver ☐ Intrahepatic bile duct ☐ Other (specify)	3427536	Using the patient's pathology/laboratory report, select the primary site of the disease. ***Note: If the primary site of the disease is not listed, proceed to Question 30a, otherwise skip to Question 31.***
30a	Other tissue or organ of origin	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Brain ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	3427536	If the primary site of the disease is not included on the previous list, provide the primary site of the disease.
31	Histological Type	☐ Hepatocellular carcinoma ☐ Intrahepatic bile duct cancer ☐ Other (specify)	3081932	Select the surgical pathology text description of the histological tumor type. ***Note: If the histological tumor type is not listed, proceed to Question 31a, otherwise, skip to Question 32.***
31a	Other histological type	_____	3294805	If the traditional surgical pathology text description of the histological tumor type is not included on the previous list, please specify the histological type.



Enrollment: Hepatocellular Carcinoma and Intrahepatic Bile Duct

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
32	Histological subtype	If Hepatocellular carcinoma: ☐ Hepatocellular carcinoma ☐ Fibrolamellar hepatocellular carcinoma ☐ Other (specify) If intrahepatic bile duct cancer: ☐ Intrahepatic cholangiocarcinoma ☐ Combined hepatocellular-cholangiocarcinoma ☐ Intraductal papillary neoplasm with an associated invasive carcinoma ☐ Mucinous cystic neoplasm with an associated invasive carcinoma ☐ Large cell neuroendocrine carcinoma ☐ Small cell neuroendocrine carcinoma ☐ Poorly differentiated neuroendocrine carcinoma ☐ Other (specify)	3081934	Using the patient's pathology/laboratory report, select the histological subtype of the primary tumor. ***Note: If the histological subtype is not listed, proceed to Question 32a, otherwise, skip to Question 33.***
32a	Other histological subtype	_____	5946219	If the histological subtype for the primary tumor is not included in the provided list, specify the histological subtype.
33	Prior malignancy (of the same cancer type)	☐ Yes ☐ No ☐ Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
34	Prior malignancy (other cancer type)	☐ Yes ☐ No ☐ Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.
35	AJCC cancer staging edition	☐ 1st ☐ 2nd ☐ 3rd ☐ 4th ☐ 5th ☐ 6th ☐ 7th ☐ 8th ☐ Not applicable	2722309	Select the AJCC staging handbook edition used to stage the patient's primary tumor.
36	AJCC clinical stage group	☐ Stage I ☐ Stage IA ☐ Stage IB ☐ Stage II ☐ Stage III ☐ Stage IIIA ☐ Stage IIIB ☐ Stage IIIC ☐ Stage IV ☐ Stage IVA ☐ Stage IVB	3440332	Using the patient's pathology/laboratory report, select the clinical stage group of the primary tumor as defined by the American Joint Committee on Cancer (AJCC), if applicable.
37	AJCC pathologic spread: Primary tumor (pT)	☐ T0 ☐ T1 ☐ T1a ☐ T1b ☐ T2 ☐ T2a ☐ T2b ☐ T3 ☐ T3a ☐ T3b ☐ T4 ☐ Tis ☐ TX	3045435	Using the patient's pathology/laboratory report, select the code for the pathologic T (primary tumor) as defined by the American Joint Committee on Cancer (AJCC).
38	AJCC pathologic spread: Lymph nodes (pN)	☐ NX ☐ N0 ☐ N1	3203106	Using the patient's pathology/laboratory report, select the code for the pathologic N (nodal) as defined by the American Joint Committee on Cancer (AJCC).
39	AJCC pathologic spread: Distant metastases (pM)	☐ M0 ☐ M1	3045439	Using the patient's pathology/laboratory report, select the code for the pathologic M (metastasis) as defined by the American Joint Committee on Cancer (AJCC).



Enrollment: Hepatocellular Carcinoma and Intrahepatic Bile Duct

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
40	AJCC tumor stage (pathological)	☐ Stage I ☐ Stage IA ☐ Stage IB ☐ Stage II ☐ Stage III ☐ Stage IIIA ☐ Stage IIIB ☐ Stage IIIC ☐ Stage IV ☐ Stage IVA ☐ Stage IVB	3045439	Using the patient's pathology/laboratory report, in conjunction with the patient's medical record, select the tumor stage as defined by the American Joint Committee on Cancer (AJCC).
41	Tumor grade	☐ GX ☐ G1 ☐ G2 ☐ G3 ☐ G4	2785839	Using the patient's pathology/laboratory report, select the grade of the primary tumor, if applicable.
42	Tumor size, largest dimension	_____cm	64215	Provide the length of the largest dimension/diameter (cm) of the primary tumor.
43	Perineural invasion present?	☐ Yes ☐ No ☐ Unavailable	3916344	Indicate if perineural invasion or infiltration of tumor or cancer is present.
44	Vascular invasion present?	☐ Yes ☐ No ☐ Unavailable	64358	Indicate whether venous invasion was present in the tumor specimen.
Hepatocellular Carcinoma Primary Tumor-specific Biospecimen Information				
45	Does the patient have a history of primary risk factor(s) for hepatocellular carcinoma?	☐ Yes ☐ No ☐ Unknown	6423770	Indicate whether additional primary hepatocellular carcinoma risk factors are documented in the patient's medical record. ***Note: If there is a history of primary risk factors proceed to Question 45a, otherwise, skip to Question 46.***
45a	Primary risk factors for hepatocellular carcinoma	☐ Alcoholic liver disease ☐ Hepatitis B ☐ Hepatitis C ☐ Hemochromatosis ☐ Non-alcoholic Fatty Liver Disease ☐ Alpha 1-Antitrypsin Deficiency ☐ Other (including rare genetic disorders, please specify)	3171846	Select all of the primary risk factors for hepatocellular carcinoma as noted in the patient's medical record. ***Note: If the primary risk factor is not listed, proceed to Question 45b, otherwise, skip to Question 46.***
45b	Other primary risk factors for hepatocellular carcinoma	_____	3171859	If not included in the previous list, specify the patient's primary risk factor(s) for hepatocellular carcinoma.
46	Was the patient treated for any of the above primary risk factors?	☐ Yes ☐ No ☐ Unknown	6423771	Indicate whether or not the patient was treated for any of their indicated primary risk factors for hepatocellular carcinoma.
47	If the patient had viral hepatitis and was treated, was there sustained virological response?	☐ Yes ☐ No ☐ Unknown ☐ Not applicable	6423783	Indicate whether there was a sustained response to treatment for viral hepatitis.
48	Additional pathologic finding(s) identified?	☐ Yes ☐ No ☐ Unknown	6423773	Indicate whether additional pathologic findings were found for this patient. ***If Hepatocellular Carcinoma additional pathologic findings were identified, continue to Question 48a. If Intrahepatic Bile Duct Cancer additional pathologic findings were identified, continue to Question 58.***



Enrollment: Hepatocellular Carcinoma and Intrahepatic Bile Duct

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
48a	Hepatocellular carcinoma additional pathologic finding(s)	☐ Fibrosis ☐ Cirrhosis ☐ Low-grade dysplastic nodule ☐ High-grade dysplastic nodule ☐ Steatosis ☐ Steatohepatitis ☐ Iron overload ☐ Chronic hepatitis ☐ Other (specify)	6423784	Select all other pathologic findings diagnosed in this patient with hepatocellular carcinoma. ***Note: If other additional pathologic findings were identified, continue to Question 48b, otherwise, skip to Question 49.***
48b	Specify other additional pathologic finding(s)	_____	6423785	If not provided in the previous list, specify all other pathologic findings diagnosed in this patient.
49	Tumor focality	☐ Multifocal ☐ Unifocal ☐ Unknown	3174022	Indicate whether the cancer first developed in a single or multiple locations.
50	Child-Pugh classification	☐ Grade A (5-6 points, well compensated disease) ☐ Grade B (7-9 points, significant functional compromise) ☐ Grade C (10-15 points, decompensated disease) ☐ Unknown	2931791	Select the grade from the Child-Pugh assessment method used in the prognosis of chronic liver disease.
51	ISHAK fibrosis score	☐ 0-No Fibrosis ☐ 1 or 2-Portal Fibrosis ☐ 3 or 4-Fibrous Septa ☐ 5-Nodular Formation and Incomplete Cirrhosis ☐ 6-Established Cirrhosis ☐ Unknown	3182621	Select the Ishak score that represents the histopathologic degree of liver damage.
52	Treatment effect	☐ No known presurgical therapy ☐ Complete necrosis (no viable tumor) ☐ Incomplete necrosis (viable tumor present) ☐ No necrosis ☐ Unknown	6423786	Indicate the treatment effect type. ***If 'Incomplete necrosis' is selected, proceed to Question 53, otherwise, skip to Question 54.***
53	Percent tumor necrosis	_____%	5455511	Provide the numeric value to represent the percentage of necrosis in the tumor submitted for HCMI.
54	Liver cancer neoadjuvant chemotherapy type	☐ Thermal ablation ☐ Transarterial chemoembolization (TACE) ☐ Not applicable	6423789	Select the neoadjuvant therapy type used to treat the liver cancer.
55	Alpha-Fetoprotein level (0-10 million ng/ml)	_____ng/mL	2932074	Provide the numerical laboratory result for alpha fetoprotein, in ng/mL.
56	Lower normal range for the Alpha-Fetoprotein level	_____ng/mL	3171861	Provide the lower limit for normal for alpha fetoprotein at your institution, in ng/mL.
57	Upper normal range for the Alpha-Fetoprotein level	_____ng/mL	2932064	Provide the upper limit for normal for alpha fetoprotein at your institution, in ng/mL.
Intrahepatic Bile Duct Cancer Primary Tumor-specific Questions				
58	Additional pathologic finding(s) identified?	☐ Yes ☐ No ☐ Unknown	6423773	Indicate whether additional pathologic findings were found for this patient. ***Note: If additional pathologic findings were identified, continue to Question 58a, otherwise, skip to Question 59.***
58a	Intrahepatic bile duct cancer additional pathologic finding(s)	☐ Fibrosis ☐ Primary sclerosing cholangitis ☐ Biliary stones ☐ Chronic hepatitis ☐ Other (specify)	6423784	Select all other pathologic findings diagnosed in this patient with intrahepatic bile duct cancer. ***Note: If the additional pathologic finding is not listed, proceed to Question 58b, otherwise, skip to Question 59.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
58b	Specify other additional pathologic finding(s)	_____	6423785	If not provided in the previous list, specify all other pathologic findings diagnosed in this patient.
59	Does the patient have any primary risk factor(s) for bile duct cancer?	☐ Yes ☐ No ☐ Unknown	6423779	Indicate whether the patient was diagnosed with any primary risk factor(s) for bile duct cancer, as noted in the patient's medical record. ***Note: If yes, proceed to Question 59a, otherwise, skip to Question 60.***
59a	Intrahepatic bile duct cancer primary risk factor(s)	☐ Alcoholic liver disease ☐ Biliary parasites ☐ Hepatitis C ☐ Nonalcoholic fatty liver disease ☐ Obesity ☐ Smoking ☐ Primary sclerosing cholangitis ☐ Recurrent pyogenic cholangitis ☐ Other (including rare genetic disorders, please specify)	6423790	Select all of the primary risk factors for intrahepatic bile duct cancer as noted in the patient's medical record. ***Note: If 'Other' is selected, proceed to Question 59b, otherwise, skip to Question 60.***
59b	Other primary risk factor(s) for bile duct cancer	_____	6423793	If not included in the previous list, specify the patient's primary risk factor(s) for bile duct cancer.
60	Has the CEA level of the patient been determined?	☐ Yes ☐ No ☐ Unknown	3107563	Indicate whether the level of carcinoembryonic antigen was determined for this patient. ***Note: If yes, proceed to Question 60a, otherwise, skip to Question 61.***
60a	CEA value	_____	2752	Provide the laboratory value of CEA for the patient. ***Note: Proceed to Question 60b.***
60b	CEA level upper limit of normal value	_____	2002247	Provide the upper level of normal for CEA in your institution's laboratory.
61	Was tumor marker CA-19-9 test performed?	☐ Yes ☐ No ☐ Unknown	2891778	Indicate whether a test for tumor marker CA-10-9 was performed for the patient's tumor. ***Note: If yes, proceed to Question 61a, otherwise, skip to Question 62.***
61a	What was the CA-19-9 value?	_____	65302	Provide the numeric result for a test sample to evaluate CA 19-9 as an indicator of presence or status of tumor or cancer.
Primary Tumor Sample Information				
62	Are you submitting a primary tumor tissue sample for this case?	☐ Yes ☐ No		***If yes, proceed to question 63, otherwise, skip to Question 79.***
63	Primary tumor biospecimen ordinal	_____	6584265	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number should be "1".***
64	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
65	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
66	Sample represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this primary tumor specimen represent the PRIMARY DIAGNOSIS for this Case ID3? ***Note: If no, proceed to Question 67, otherwise, skip to Question 68.***
67	Specify the ICD-10 code	_____	3226287	Provide the ICD-10 code for the primary tumor used to generate the model submitted to HCMI.
68	Tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the tumor tissue sample collected for molecular characterization.
69	Anatomic site of tumor from which model was derived	☐ Liver ☐ Common bile duct ☐ Common hepatic duct ☐ Lung ☐ Bone ☐ Brain ☐ Other (specify)	4214629	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI. ***Note: If the tissue or organ of origin is not listed, proceed to Question 69a. Otherwise, skip to Question 70.***
69a	Other anatomic site from which the tumor was obtained	_____	5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.
70	Method of cancer sample procurement	☐ Wedge resection ☐ Partial hepatectomy-major ☐ Partial hepatectomy-minor ☐ Total hepatectomy ☐ Needle biopsy ☐ Other Method (specify)	3103514	Provide the procedure performed to obtain the primary tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 70a, otherwise, skip to Question 71.***
70a	Specify the other method of tumor sample procurement	_____	2006730	Specify the procedure performed to obtain the primary tumor tissue, if not included in the previous list.
71	Number of days from index date to date of tumor sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the tumor tissue submitted for HCMI.
72	Tumor tissue type	☐ Primary ☐ Additional Primary ☐ NOS	3288124	Provide the primary tumor tissue type for this sample.
Primary Tumor Model Information				
73	Primary model biospecimen ordinal	_____	6594596	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number is expected to be "1".***
74	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
75	BPC submitter ID (if available)		6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
76	Model represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this MODEL represent the PRIMARY DIAGNOSIS for this Case ID3?



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
77	Model's primary tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the PRIMARY TUMOR TISSUE from which this model is derived.
78	Model's primary tumor biospecimen ordinal	_____	6584265	Enter the biospecimen ordinal of the PRIMARY TUMOR TISSUE from which this model is derived.
Treatment Information				
79	History of neoadjuvant treatment	☐ No ☐ Yes; radiation prior to resection ☐ Yes; pharmaceutical treatment prior to resection ☐ Yes; both radiation and pharmaceutical treatment prior to resection ☐ Unknown	3382737	Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment. ***Note: Radiation therapy is addressed in Questions 87-88. Pharmaceutical therapy is addressed in Questions 80-86.***
80	Neoadjuvant chemotherapy type	☐ Cytotoxic chemotherapy ☐ Hormonal ☐ Immunotherapy (cellular and immune checkpoint) ☐ Targeted therapy (small molecule inhibitors and targeted antibodies) ☐ Not applicable	5832928	Select all neoadjuvant chemotherapy types that were administered to the patient. ***Note: Cytotoxic chemotherapy is addressed in Questions 81-82. Immunotherapy is addressed in Questions 83-84. Targeted therapy is addressed in Questions 85-86.***
81	Neoadjuvant chemotherapeutic regimen	☐ 5-Fluorouracil ☐ Capecitabine ☐ Cisplatin ☐ Doxorubicin ☐ FOLFOX (5-FU/Leucovorin/Oxaliplatin) ☐ Gemcitabine ☐ GEMOX (Gemcitabine/Oxaliplatin) ☐ Oxaliplatin ☐ TS-1 ☐ Other (specify) ☐ Chemotherapy not given	2853313	Select all chemotherapeutics used for neoadjuvant therapy. ***Note: If neoadjuvant chemotherapy was not given, skip to Question 83. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 81a, otherwise, skip to Question 82.***
81a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapies administered.
82	Days to neoadjuvant chemotherapy treatment from index date	_____	5102411	Provide the number of days from index date to the date of treatment with neoadjuvant chemotherapy.
83	Specify immunotherapy	_____	2953828	Provide the name of the immunotherapy administered to the patient.
84	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
85	Targeted therapy	☐ Brivanib ☐ Everolimus ☐ Linifanib ☐ PTK787 ☐ Ramucirumab ☐ Regorafenib ☐ Sorafenib ☐ Other (specify)	6428117	Select the targeted molecular therapy administered to the patient. ***Note: If the targeted molecular therapy is not listed, proceed to Question 85a, otherwise, skip to Question 86.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
85a	Specify targeted therapy	_____	4308476	Provide the name of the targeted therapy administered to the patient.
86	Days to targeted therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with targeted therapy.
87	Radiation therapy administered type	☐ 2D conventional ☐ 3D conformal ☐ Brachytherapy HDR ☐ Brachytherapy LDR ☐ IMRT ☐ Proton Beam ☐ Stereotactic Body RT ☐ Stereotactic Radiosurgery ☐ WBRT ☐ Other (specify) ☐ Unspecified ☐ Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. ***Note: If radiation therapy was not administered, proceed to Question 89. If the radiation therapy is not listed, proceed to Question 87a, otherwise, skip to Question 88.***
87a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
88	Days to radiation treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with radiation therapy.
Metastatic/Recurrent Tumor Biospecimen Information				
89	Are you submitting a metastatic/recurrent tumor tissue sample?	☐ Yes ☐ No		A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen. ***Note: If yes, proceed to Question 90. If no, proceed to Question 161.***
90	Metastatic tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1", the second should be number "2", etc.***
91	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
92	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
93	Metastatic/recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
94	Number of days from index date to date of diagnosis of metastasis/recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic/recurrent disease.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
95	Method of metastatic/ recurrent cancer sample procurement	☐ Wedge resection ☐ Partial hepatectomy-major ☐ Partial hepatectomy-minor ☐ Total hepatectomy ☐ Needle biopsy ☐ Other Method (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 95a, otherwise, skip to Question 96.***
95a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
96	Number of days from index date to date of metastatic/recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
97	Metastatic/recurrent site	☐ Bone ☐ Brain ☐ Intrahepatic bile duct ☐ Liver ☐ Lung ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 97a, otherwise, skip to Question 98.***
97a	Other metastatic/ recurrent site	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
98	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
99	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
100	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
101	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
102	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
103	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
104	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
105	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
106	Histological type	☐ Hepatocellular carcinoma ☐ Intrahepatic cholangiocarcinoma ☐ Other (specify)	3081932	Provide the traditional surgical pathology text description of the histological tumor type. ***If the histological type is not listed, proceed to Question 106a, otherwise, skip to Question 107.***
106a	Other histological type	_____	3294805	If the traditional surgical pathology text description of the histological tumor type is not included on the previous list, please specify the histological type.
Metastatic/Recurrent Hepatocellular Carcinoma Tumor-specific Questions				
107	Tumor size, largest dimension	_____(cm)	64215	Provide the length of the largest dimension/diameter of the primary tumor.
108	Perineural invasion present?	☐ Yes ☐ No ☐ Unavailable	3916344	Indicate if perineural invasion or infiltration of tumor or cancer is present.
109	Vascular invasion present?	☐ Yes ☐ No ☐ Unknown	64358	Indicate whether venous invasion was present in the tumor specimen.
110	Additional pathologic finding(s) identified?	☐ Yes ☐ No ☐ Unknown	6423773	Indicate whether additional pathologic findings were found for this patient. ***Note: If additional pathologic findings were found, proceed to Question 110a, otherwise, skip to Question 111.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
110a	Hepatocellular carcinoma additional pathologic finding(s)	☐ Fibrosis ☐ Cirrhosis ☐ Low-grade dysplastic nodule ☐ High-grade dysplastic nodule ☐ Steatosis ☐ Steatohepatitis ☐ Iron overload ☐ Chronic hepatitis ☐ Other (specify)	6423784	Select all other pathologic findings diagnosed in this patient with hepatocellular carcinoma. ***Note: If other additional pathologic findings were identified, continue to Question 110b, otherwise, skip to Question 111.***
110b	Specify other additional pathologic finding(s)	_____	6423785	If not provided in the previous list, specify all other pathologic findings diagnosed in this patient.
111	Alpha-Fetoprotein level (0-10 million ng/ml)	_____ng/mL	2932074	Provide the numerical laboratory result for alpha fetoprotein, in ng/mL.
112	Lower normal range for the Alpha-Fetoprotein level	_____ng/mL	3171861	Provide the lower limit for normal for alpha fetoprotein at your institution, in ng/mL.
113	Upper normal range for the Alpha-Fetoprotein level	_____ng/mL	2932064	Provide the upper limit for normal for alpha fetoprotein at your institution, in ng/mL.
Metastatic/Recurrent Intrahepatic Cholangiocarcinoma Tumor-specific Questions				
114	Tumor size, largest dimension	_____(cm)	64215	Provide the length of the largest dimension/diameter of the primary tumor.
115	Perineural invasion present?	☐ Yes ☐ No ☐ Unavailable	3916344	Indicate if perineural invasion or infiltration of tumor or cancer is present.
116	Vascular invasion present?	☐ Yes ☐ No ☐ Unknown	64358	Indicate whether venous invasion was present in the tumor specimen.
117	Additional pathologic finding(s) identified?	☐ Yes ☐ No ☐ Unknown	6423773	Indicate whether additional pathologic findings were found for this patient. ***Note: If additional pathologic findings were found, proceed to Question 117a, otherwise, skip to Question 118.***
117a	Intrahepatic bile duct cancer additional pathologic finding(s)	☐ Fibrosis ☐ Primary sclerosing cholangitis ☐ Biliary stones ☐ Chronic hepatitis ☐ Other (specify)	6423784	Select all other pathologic findings diagnosed in this patient with intrahepatic bile duct cancer. ***Note: If other additional pathologic findings were identified, continue to Question 117b, otherwise, skip to Question 118.***
117b	Specify other additional pathologic finding(s)	_____	6423785	If not provided in the previous list, specify all other pathologic findings diagnosed in this patient.
118	Has the CEA level of the patient been determined?	☐ Yes ☐ No ☐ Unknown	3107563	Indicate whether the level of carcinoembryonic antigen was determined for this patient. ***Note: If yes, proceed to Question 118a, otherwise, skip to Question 119.***
118a	CEA value	_____	2752	Provide the laboratory value of CEA for the patient. ***Note: Proceed to Question 118b.***
118b	CEA level upper limit of normal value	_____	2002247	Provide the upper level of normal for CEA in your institution's laboratory.
119	Was tumor marker CA-19-9 test performed?	☐ Yes ☐ No ☐ Unknown	2891778	Indicate whether a test for tumor marker CA-10-9 was performed for the patient's tumor. ***Note: If yes, proceed to Question 119a, otherwise, skip to Question 120.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
119a	What was the CA-19-9 value?	_____	65302	Provide the numeric result for a test sample to evaluate CA 19-9 as an indicator of presence or status of tumor or cancer.
Additional Metastatic/Recurrent Tumor Biospecimen Information				
120	Are you submitting a second metastatic/recurrent tumor tissue sample?	☐ Yes ☐ No		***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen. If yes, proceed to Question 121, otherwise, skip to Question 151.***
121	Metastatic tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1", the second should be number "2", etc.***
122	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
123	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
124	Metastatic/recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
125	Number of days from index date to date of diagnosis of metastasis/recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic/recurrent disease.
126	Method of metastatic/ recurrent cancer sample procurement	☐ Wedge resection ☐ Partial hepatectomy-major ☐ Partial hepatectomy-minor ☐ Total hepatectomy ☐ Needle biopsy ☐ Other Method (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 126a, otherwise, skip to Question 127.***
126a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
127	Number of days from index date to date of metastatic/recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
128	Metastatic/recurrent site	☐ Bone ☐ Brain ☐ Intrahepatic bile duct ☐ Liver ☐ Lung ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 128a, otherwise, skip to Question 129.***
128a	Other metastatic/ recurrent site	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
129	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
130	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
131	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
132	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
133	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
134	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
135	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
136	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
137	Histological type	☐ Hepatocellular carcinoma ☐ Intrahepatic cholangiocarcinoma ☐ Other (specify)	3081932	Provide the traditional surgical pathology text description of the histological tumor type. ***If the histological type is not listed, proceed to Question 137a, otherwise, skip to Question 138.***
137a	Other histological type	_____	3294805	If the traditional surgical pathology text description of the histological tumor type is not included on the previous list, please specify the histological type.
Additional Metastatic/Recurrent Hepatocellular Carcinoma Tumor-specific Questions				
138	Tumor size, largest dimension	_____(cm)	64215	Provide the length of the largest dimension/diameter of the primary tumor.
139	Perineural invasion present?	☐ Yes ☐ No ☐ Unavailable	3916344	Indicate if perineural invasion or infiltration of tumor or cancer is present.
140	Vascular invasion present?	☐ Yes ☐ Unknown ☐ No	64358	Indicate whether venous invasion was present in the tumor specimen.
141	Additional pathologic finding(s) identified?	☐ Yes ☐ No ☐ Unknown	6423773	Indicate whether additional pathologic findings were found for this patient. ***Note: If additional pathologic findings were found, proceed to Question 141a, otherwise, skip to Question 142.***
141a	Hepatocellular carcinoma additional pathologic finding(s)	☐ Fibrosis ☐ Steatohepatitis ☐ Cirrhosis ☐ Iron overload ☐ Low-grade dysplastic nodule ☐ Chronic hepatitis ☐ High-grade dysplastic nodule ☐ Other (specify) ☐ Steatosis	6423784	Select all other pathologic findings diagnosed in this patient with hepatocellular carcinoma. ***Note: If other additional pathologic findings were identified, continue to Question 141b, otherwise, skip to Question 142.***
141b	Specify other additional pathologic finding(s)	_____	6423785	If not provided in the previous list, specify all other pathologic findings diagnosed in this patient.
142	Alpha-Fetoprotein level (0-10 million ng/ml)	_____ng/mL	2932074	Provide the numerical laboratory result for alpha fetoprotein, in ng/mL.
143	Lower normal range for the Alpha-Fetoprotein level	_____ng/mL	3171861	Provide the lower limit for normal for alpha fetoprotein at your institution, in ng/mL.
144	Upper normal range for the Alpha-Fetoprotein level	_____ng/mL	2932064	Provide the upper limit for normal for alpha fetoprotein at your institution, in ng/mL.



Enrollment: Hepatocellular Carcinoma and Intrahepatic Bile Duct

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Additional Metastatic/Recurrent Intrahepatic Cholangiocarcinoma Tumor-specific Questions				
145	Tumor size, largest dimension	_____(cm)	64215	Provide the length of the largest dimension/diameter of the primary tumor.
146	Perineural invasion present?	☐ Yes ☐ No ☐ Unavailable	3916344	Indicate if perineural invasion or infiltration of tumor or cancer is present.
147	Vascular invasion present?	☐ Yes ☐ Unknown ☐ No	64358	Indicate whether venous invasion was present in the tumor specimen.
148	Additional pathologic finding(s) identified?	☐ Yes ☐ No ☐ Unknown	6423773	Indicate whether additional pathologic findings were found for this patient. ***Note: If additional pathologic findings were found, proceed to Question 148a, otherwise, skip to Question 149.***
148a	Intrahepatic bile duct cancer additional pathologic finding(s)	☐ Fibrosis ☐ Primary sclerosing cholangitis ☐ Biliary stones ☐ Chronic hepatitis ☐ Other (specify)	6423784	Select all other pathologic findings diagnosed in this patient with intrahepatic bile duct cancer. ***Note: If other additional pathologic findings were identified, continue to Question 148b, otherwise, skip to Question 149.***
148b	Specify other additional pathologic finding(s)	_____	6423785	If not provided in the previous list, specify all other pathologic findings diagnosed in this patient.
149	Has the CEA level of the patient been determined?	☐ Yes ☐ No ☐ Unknown	3107563	Indicate whether the level of carcinoembryonic antigen was determined for this patient. ***Note: If yes, proceed to Question 149a, otherwise, skip to Question 150.***
149a	CEA value	_____	2752	Provide the laboratory value of CEA for the patient. ***Note: Proceed to Question 149b.***
149b	CEA level upper limit of normal value	_____	2002247	Provide the upper level of normal for CEA in your institution's laboratory.
150	Was tumor marker CA-19-9 test performed?	☐ Yes ☐ No ☐ Unknown	2891778	Indicate whether a test for tumor marker CA-10-9 was performed for the patient's tumor. ***Note: If yes, proceed to Question 150a, otherwise, skip to Question 151.***
150a	What was the CA-19-9 value?	_____	65302	Provide the numeric result for a test sample to evaluate CA 19-9 as an indicator of presence or status of tumor or cancer.
Metastatic/Recurrent Tumor Model Information				
151	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
152	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
153	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.



Enrollment: Hepatocellular Carcinoma and Intrahepatic Bile Duct

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
154	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
155	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Additional Metastatic/Recurrent Tumor Model Information				
156	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
157	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
158	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
159	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
160	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Other Biospecimen Information				
161	Are you submitting an OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an OTHER tissue sample (e.g. pre-malignant, non-malignant, or dysplastic tissue, etc.) was collected for HCMI for this case. ***Note: If yes, proceed to Question 162.***
162	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
163	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
164	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
165	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the procedure performed to obtain the OTHER tissue.



Enrollment: Hepatocellular Carcinoma and Intrahepatic Bile Duct

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
166	Method of OTHER tissue sample procurement	☐ Wedge resection ☐ Partial hepatectomy-major ☐ Partial hepatectomy-minor ☐ Total hepatectomy ☐ Needle biopsy ☐ Other Method (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 166a, otherwise, skip to Question 167.***
166a	Other method of cancer sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
167	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
168	Tissue type	☐ Non-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 168a, otherwise, skip to Question 169.***
168a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
169	Anatomic site of OTHER tissue	☐ Lung ☐ Bone ☐ Brain ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 169a, otherwise, skip to Question 170.***
169a	Specify anatomic site of OTHER tissue	_____	6584916	If not included in the previous list, specify the site from which the OTHER tissue used to develop the model was derived.
170	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
171	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Additional OTHER Tissue Biospecimen Information				
172	Are you submitting an additional OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an OTHER tissue sample (e.g. pre-malignant, non-malignant, or dysplastic tissue, etc.) was collected for HCMI for this case. ***Note: If yes, proceed to Question 173, otherwise, skip to Question 183.***
173	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
174	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.



Enrollment: Hepatocellular Carcinoma and Intrahepatic Bile Duct

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
175	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
176	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the procedure performed to obtain the OTHER tissue.
177	Method of OTHER tissue sample procurement	☐ Wedge resection ☐ Partial hepatectomy-major ☐ Partial hepatectomy-minor ☐ Total hepatectomy ☐ Needle biopsy ☐ Other Method (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 177a, otherwise, skip to Question 178.***
177a	Other method of cancer sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
178	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
179	Tissue type	☐ Non-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 179a, otherwise, skip to Question 180.***
179a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
180	Anatomic site of OTHER tissue	☐ Lung ☐ Bone ☐ Brain ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 180a, otherwise, skip to Question 181.***
180a	Specify anatomic site of OTHER tissue	_____	6584916	If not included in the previous list, specify the site from which the OTHER tissue used to develop the model was derived.
181	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
182	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Other Tissue Model Information				
183	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
184	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.



Enrollment: Hepatocellular Carcinoma and Intrahepatic Bile Duct

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
185	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
186	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
187	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.
Additional Other Tissue Model Information (if applicable)				
188	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
189	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
190	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
191	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
192	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.



Enrollment: Kidney

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Form Notes: An Enrollment Form should be completed for each HCMI case upon qualification notice from Leidos. All information provided on this form should include activity from the Date of Initial Pathologic Diagnosis to the most recent Date of Last Contact with the patient.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	☐ Initial pathologic diagnosis ☐ Sample procurement ☐ First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.
Patient Information				
4	Gender	☐ Male ☐ Female ☐ Unspecified	2200604	Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
5	Height	_____	649	Provide the patient's height, in centimeters.
6	Weight	_____	651	Provide the patient's weight, in kilograms.
7	Body mass index (BMI)	_____	2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
8	Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown ☐ Not reported	2192199	Provide the patient's race using the defined categories. **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 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. **Black or African American:** A person having origins in any of the black racial groups of Africa. **Native Hawaiian or other Pacific Islander:** A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island. **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
9	Ethnicity	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Not reported	2192217	Provide the patient's ethnicity using the defined categories. **Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. **Not Hispanic or Latino:** A person not meeting the definition of Hispanic or Latino.



Enrollment: Kidney

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
10	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.
11	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. ***Note: If the patient's age is greater than 32,872 days (90 years), please enter 32,872.***
12	Year of birth	_____	2896954	Provide the year of the patient's birth. If the patient was born prior to 1928, insert the date 1928.
13	Family history of cancer	☐ Same ☐ Different ☐ None ☐ Unknown	5832923	Has a first-degree relative of the patient been diagnosed with a cancer of the same or a different type?
14	Smoking history	☐ Lifelong non-smoker (<100 cigarettes smoked in a lifetime) ☐ Current smoker (includes daily and non-daily smokers) ☐ Current reformed smoker (duration not specified) ☐ Current reformed smoker for >15 years ☐ Current reformed smoker for ≤15 years	2181650	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories.
15	Metastasis at diagnosis assessment status	☐ Metastatic ☐ Non-metastatic (confirmed) ☐ Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor. ***Note: If metastatic at diagnosis, proceed to Question 16, otherwise, skip to Question 17.***
16	Metastatic site(s) at diagnosis	☐ Adrenal gland, contralateral ☐ Adrenal gland, ipsilateral ☐ Lung ☐ Bone ☐ Lymph node(s) ☐ Brain ☐ Liver ☐ Pancreas ☐ Other (specify)	3108271	Indicate the site(s) of metastasis at the time of diagnosis of the primary tumor. ***Note: If the anatomic site of tumor tissue is not listed, proceed to Question 16a, otherwise, skip to Question 17.***
16a	Specify metastatic site(s)	_____	3128033	If the site of metastasis is not included on the provided list, specify the site of metastasis.
17	Inherited cancer susceptibility syndromes	☐ von Hippel-Lindau Syndrome ☐ BAP1 mutant disease ☐ PTEN hamartoma syndrome (Cowden syndrome) ☐ SDH associated renal cancer ☐ Hereditary papillary renal cell carcinoma ☐ Hereditary leiomyoma-renal cell carcinoma ☐ Birt-Hogg-Dube syndrome ☐ Familial renal cancer ☐ Tuberous sclerosis ☐ Hereditary renal oncocytoma	6002201	Select all hereditary cancer predisposition syndromes with which the patient has been diagnosed.
Biospecimen Information				
18	Tissue sample type(s) collected for HCMI for this case	☐ Normal tissue ☐ Primary tumor ☐ Metastatic ☐ Recurrent ☐ Other tissue	2006911	Please select all the tissue sample types submitted for HCMI with this case.



Enrollment: Kidney

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
19	Number of NORMAL tissues biospecimens collected for HCMI for this case	_____	6584256	Please provide the number of normal tissue specimens obtained for HCMI for this case. ***Note: This number is expected to be 1.***
20	Number of PRIMARY cancer tissue biospecimens collected for HCMI model development for this case	_____	6584257	Please provide the number of primary tumor specimens obtained for HCMI for this case. ***Note: A single primary tumor biospecimen obtained that is portioned for both sequencing and model generation counts as 1 single primary tumor specimen. This number is expected to be 1.***
21	Number of METASTATIC/RECURRENT cancer tissue biospecimens collected for HCMI model development for this case	_____	6584258	Please provide the number of metastatic and/or recurrent cancer biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
22	Number of OTHER tissue biospecimens collected for HCMI model development for this case	_____	6584259	Please provide the number of pre-malignant, non-malignant, or dysplastic tissue biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
23	Total number of tissue biospecimens collected for HCMI for this case	_____	6584271	Please provide the total number of tissue biospecimens collected for HCMI for this case. ***Note: This number should be the sum of the normal, primary tumor, metastatic/ recurrent tumor, and other biospecimen counts above.***
Normal Control Information				
24	Normal tissue biospecimen ordinal	_____	6584264	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
25	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
26	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
27	Type of normal control	☐ Whole blood ☐ Buccal cells ☐ Buffy coat ☐ Lymphocytes ☐ Extracted DNA from blood ☐ Extracted DNA from saliva ☐ Extracted DNA from buccal cells ☐ Extracted DNA from normal tissue ☐ FFPE non-neoplastic tissue ☐ Non-neoplastic tissue	3081936	Indicate the type of normal control submitted for this case.



Enrollment: Kidney

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
28	Anatomic site of normal tissue	☐ Kidney ☐ Other (specify) ☐ Not applicable	4132152	If non-neoplastic tissue was submitted as the normal control, select the anatomic site of the normal tissue. ***Note: If the anatomic site of normal tissue is not listed, proceed to Question 28a, otherwise, skip to Question 29.***
28a	Other anatomic site of normal tissue	_____	3288189	If non-neoplastic tissue, adjacent tissue, or normal tissue from another anatomic site was submitted as the normal control, provide the anatomic site of the normal tissue.
29	Distance from tumor to normal control tissue (if not blood)	☐ Adjacent (< or = 2cm) ☐ Distal (>2cm) ☐ Unknown ☐ Not applicable	3088708	Indicate the distance from the site of normal tumor collection to the primary tumor. ***Note: If normal tissue was not submitted, select 'Not applicable'.***
30	Normal tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the normal tissue sample collected for molecular characterization.
Primary Tumor Biospecimen Information				
31	ICD-10 code for primary tumor	☐ C64.1 ☐ C64.2 ☐ C64.9 ☐ Other (specify)	3226287	Provide the ICD-10 code for the primary tumor as used to generate the ID3 for this subject. ***Note: If the ICD-10 code is not listed, proceed to 31a, otherwise, skip to Question 32.***
31a	Other ICD-10 code for primary tumor	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.
32	Tumor morphology	☐ 8260/3 ☐ 8311/3 ☐ 8312/3 ☐ 8316/3 ☐ 8317/3 ☐ 8319/3 ☐ 8480/3 ☐ Other (specify)	3226275	Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor. ***Note: If the ICD-O-3 histology code of the primary tumor is not listed, proceed to Question 32a, otherwise, skip to Question 33.***
32a	Specify other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.
33	Tissue or organ of origin	☐ Kidney ☐ Other (specify)	3427536	Using the patient's pathology/laboratory report, select the primary site of the disease. ***Note: If the primary site of the disease is not listed, proceed to Question 33a, otherwise skip to Question 34.***
33a	Other tissue or organ of origin	_____	5946219	If the primary site of the disease is not included on the previous list, provide the primary site of the disease.
34	Histological type	☐ Kidney cancer ☐ Other (specify)	3081932	Select the surgical pathology text description of the histological tumor type. ***Note: If the histological tumor type is not listed, proceed to Question 34a, otherwise, skip to Question 35.***
34a	Other histological type	_____	3294805	If the traditional surgical pathology text description of the histological tumor type is not included on the previous list, please specify the histological type.



Enrollment: Kidney

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
35	Histological subtype	☐ Clear cell renal cell carcinoma ☐ Multilocular cystic clear cell renal cell neoplasm of low malignant potential ☐ Papillary renal cell carcinoma ☐ Papillary renal cell carcinoma, Type 1 ☐ Papillary renal cell carcinoma, Type 2 ☐ Chromophobe renal cell carcinoma ☐ Collecting duct carcinoma ☐ Renal medullary carcinoma ☐ MiT family translocation renal cell carcinoma ☐ Xp11 translocation renal cell carcinoma ☐ t(6;11) renal cell carcinoma ☐ Mucinous tubular and spindle renal cell carcinoma ☐ Tubulocystic renal cell carcinoma ☐ Acquired cystic disease associated renal cell carcinoma ☐ Clear cell papillary renal cell carcinoma ☐ Hereditary leiomyomatosis and renal cell carcinoma-associated renal cell carcinoma ☐ Succinate dehydrogenase (SDH) deficient renal cell carcinoma ☐ Renal cell carcinoma, unclassified ☐ Other (specify, CDE ID: 3124492)	3081934	Using the patient's pathology/laboratory report, select the histological subtype of the primary tumor. ***Note: If the histological subtype is not listed, proceed to Question 35a, otherwise, skip to Question 36.***
35a	Other histological subtype	_____	3124492	If the histological subtype for the primary tumor is not included in the provided list, specify the histological subtype.
36	Prior malignancy (of the same cancer type)	☐ Yes ☐ No ☐ Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
37	Prior malignancy (other cancer type)	☐ Yes ☐ No ☐ Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.
38	AJCC cancer staging edition	☐ 1st ☐ 2nd ☐ 3rd ☐ 4th ☐ 5th ☐ 6th ☐ 7th ☐ 8th	2722309	Select the AJCC staging handbook edition used to stage the patient's primary tumor.
39	Clinical stage group	☐ Stage I ☐ Stage II ☐ Stage III ☐ Stage IV	3440332	Using the patient's pathology/laboratory report, select the clinical stage group of the primary tumor as defined by the American Joint Committee on Cancer (AJCC).
40	AJCC pathologic spread: Primary tumor (pT)	☐ TX ☐ T0 ☐ T1 ☐ T1a ☐ T1b ☐ T2 ☐ T2a ☐ T2b ☐ T3 ☐ T3a ☐ T3b ☐ T3c ☐ T4	3045435	Using the patient's pathology/laboratory report, select the code for the pathologic T (primary tumor) as defined by the American Joint Committee on Cancer (AJCC).
41	AJCC pathologic spread: Lymph nodes (pN)	☐ N0 ☐ N1 ☐ NX	3203106	Using the patient's pathology/laboratory report, select the code for the pathologic N (nodal) as defined by the American Joint Committee on Cancer (AJCC).



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42	AJCC pathologic spread: Distant metastases (pM)	☐ M0 ☐ M1	3045439	Using the patient's pathology/laboratory report, select the code for the pathologic M (metastasis) as defined by the American Joint Committee on Cancer (AJCC).
43	Tumor stage (pathological)	☐ Stage I ☐ Stage II ☐ Stage III ☐ Stage IV	3065862	Using the patient's pathology/laboratory report, in conjunction with the patient's medical record, select the stage as defined by the American Joint Committee on Cancer (AJCC).
44	Tumor grade	☐ G1 ☐ G4 ☐ G2 ☐ GX ☐ G3	2785839	Using the patient's pathology/laboratory report, select the grade of the primary tumor.
Prognostic/Predictive/Lifestyle Features for Primary Tumor Prognosis or Responsiveness to Treatment				
45	Sarcomatoid features	☐ Yes, value available (specify) ☐ Yes, value not specified ☐ Not identified	5334382	Indicate whether histologic features of a sarcomatous component (pattern of dedifferentiation) were present in the primary tumor. ***Note: if the percentage of sarcomatoid features is known, proceed to Question 45a, otherwise, skip to Question 46.***
45a	If sarcomatoid features are present, indicate the percentage	_____%	6790124	Specify the percentage of the sarcomatoid features present in the patient's cancer.
46	Rhabdoid features	☐ Yes, value available (specify) ☐ Yes, value not specified ☐ Not identified	6790118	Indicate whether histologic features of a rhabdoid component were present in the primary tumor. ***Note: if the percentage of rhabdoid features is known, proceed to Question 46a, otherwise, skip to Question 47.***
46a	If rhabdoid features are present, indicate the percentage	_____%	6790119	Specify the percentage of the rhabdoid features present in the patient's cancer.
47	Tumor necrosis	☐ Yes, value available (specify) ☐ Yes, value not specified ☐ Not identified	6790121	Indicate whether histologic features of necrosis were present in the primary tumor. ***Note: if the percentage of necrotic features is known, proceed to Question 47a, otherwise, skip to Question 48.***
47a	If tumor necrosis is present, indicate the percentage	_____%	6790122	Specify the percentage of necrosis present in the patient's cancer.
48	Lymphovascular invasion	☐ Present ☐ Absent ☐ Cannot be determined	64727	Indicate if large vessel (vascular) invasion or small, thin-walled (lymphatic) invasion was detected in a tumor specimen.
49	Number of positive lymph nodes	_____	89	Provide the number of lymph nodes with disease involvement.
50	Number of lymph nodes tested	_____	3	Provide the total number of lymph nodes tested for the presence of cancer cells.
51	Additional pathologic findings	☐ Cyst(s) (specify type) ☐ Tubular (papillary) adenoma(s) ☐ Other (specify)	6790126	Indicate all additional pathologic findings present in the patient. ***Note: if cyst(s) were identified, proceed to Question 51a. If the pathologic finding is not listed, proceed to Question 51b, otherwise, skip to Question 52.***
51a	Specify type of cyst(s)	_____	6790127	Identify additional pathologic findings of a cyst identified in a patient.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
51b	Specify other additional pathologic findings	_____	6790128	If not included in the previous list, specify any additional pathologic findings.
52	Tumor size, largest dimension	_____cm	64215	Provide the largest dimension of the primary tumor in cm, regardless of anatomical plane.
53	Tumor focality	☐ Unifocal ☐ Multifocal ☐ Unknown	3174022	Indicate whether the tumor or cancer first developed in a single or multiple locations.
54	Tumor site	☐ Upper pole ☐ Middle ☐ Lower pole ☐ Not specified ☐ Other (specify)	6790129	Indicate the primary site of cancer in the kidney. ***Note: If the tumor site is not listed, proceed to Question 54a, otherwise, skip to Question 55.***
54a	Specify other tumor site	_____	6790130	If not included in the previous list, specify the primary site of cancer in the kidney.
55	Tumor extension	☐ No evidence of primary tumor ☐ Tumor limited to kidney ☐ Tumor extension into perinephric tissue (beyond renal capsule) ☐ Tumor extension into renal sinus ☐ Tumor extension beyond Gerota's fascia ☐ Tumor extension into major vein (renal vein or its segmental branches, inferior vena cava) ☐ Tumor extension into pelvicalyceal system ☐ Tumor extension into adrenal gland, direct invasion ☐ Tumor extension into adrenal gland, noncontiguous ☐ Tumor extension into other organ(s)/structure(s) (specify) ☐ Cannot be assessed	6790131	Identify the extent to which a kidney tumor has invaded through the wall of an organ into surrounding organs and/or adjacent tissues. ***Note: If tumor extension is into other organ(s)/structure(s), proceed to Question 55a, otherwise, skip to Question 56.***
55a	Specify other organ(s)/structure(s)	_____	6790132	If not included in the previous list, specify the name of other organs to which the kidney tumor has invaded.
56	Margins	☐ Cannot be assessed ☐ Uninvolved by invasive carcinoma ☐ Involved by invasive carcinoma	2199871	Indicate the status of the circumferential margin of surgical resection. ***Note: If the margin is involved by invasive carcinoma, proceed to Question 57, otherwise, skip to Question 58.***
57	If margins involved by invasive carcinoma, specify margin	☐ Renal parenchymal margin (partial nephrectomy only) ☐ Renal capsular martin (partial nephrectomy only) ☐ Perinephric fat margin ☐ Renal sinus soft tissue margin ☐ Gerota's fascial margin ☐ Renal vein margin ☐ Ureteral margin ☐ Other (specify)	6790133	Indicate the margin type that has been involved by invasive carcinoma. ***Note: If the margin is not listed, proceed to Question 57a, otherwise, skip to Question 58.***
57a	Specify other margin	_____	6790134	If not included in the previous list, specify the margin type.
58	Residual tumor	☐ RX ☐ R1 ☐ R0 ☐ R2	2608702	Indicate the status of the tissue margin following surgical resection.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
59	Pathologic findings in nonneoplastic kidney	☐ Insufficient tissue ☐ None identified ☐ Glomerular disease (specify) ☐ Tubulointerstitial disease (specify) ☐ Vascular disease (specify) ☐ Other (specify)	6790135	Indicate pathologic findings identified in the patient's non-neoplastic kidney. ***Note: If pathologic findings in nonneoplastic kidney were identified, proceed to Question 59a, otherwise, skip to Question 60.***
59a	Specify pathologic findings in nonneoplastic kidney	_____	6790136	Specify the additional pathologic findings identified in the patient's non-neoplastic kidney.
Primary Tumor Clinical Molecular Characterization				
60	Was VHL mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6790137	Indicate whether or not an analysis for mutation in the VHL gene was performed. ***Note: If VHL mutation analysis was performed, proceed to Question 61, otherwise, skip to Question 65.***
61	Was a germline mutation in VHL identified?	☐ Yes ☐ No	6790146	Indicate whether or not a mutation in the VHL gene was identified. ***Note: If a mutation was identified, proceed to Question 62, otherwise, skip to Question 65.***
62	If a mutation was identified, indicate the type of mutation	☐ Frameshift insertion (specify) ☐ Frameshift deletion (specify) ☐ In-frame insertion (specify) ☐ In-frame deletion (specify) ☐ Nonsense (specify) ☐ Missense (specify) ☐ Splicing mutation (specify) ☐ Other (specify)	6790236	Indicate the type of mutation identified while performing VHL gene mutation analysis. ***Note: If the mutation type is not listed, proceed to Question 62a, otherwise, skip to Question 63.***
62a	Specify the other type of mutation	_____	6790245	If not provided in the previous list, specify the type of mutation identified while performing VHL gene mutation analysis.
63	Specify the VHL mutation	_____	6790147	Specify the germline mutation that was identified while performing the VHL gene mutation analysis.
64	Mutation identification method	☐ Next generation targeted sequencing ☐ Whole exome sequencing ☐ Not performed ☐ Other (specify)	6003729	Indicate the method that was used to perform VHL gene mutation analysis. ***Note: If the mutation identification method is not listed, proceed to Question 64a, otherwise, skip to Question 65.***
64a	Specify other mutation identification method	_____	6002204	If not provided in the previous list, specify the method that was used to perform VHL gene mutation analysis.
65	Was FH mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6790138	Indicate whether or not an analysis for mutation in the FH gene was performed. ***Note: If FH mutation analysis was performed, proceed to Question 66, otherwise, skip to Question 69.***
66	Was a mutation in FH identified?	☐ Yes ☐ No	6790148	Indicate whether or not a mutation in the FH gene was identified. ***Note: If a mutation was identified, proceed to Question 67, otherwise, skip to Question 69.***
67	If a mutation was identified, indicate the type of mutation	☐ Frameshift insertion (specify) ☐ Frameshift deletion (specify) ☐ In-frame insertion (specify) ☐ In-frame deletion (specify) ☐ Nonsense (specify) ☐ Missense (specify) ☐ Splicing mutation (specify) ☐ Other (specify)	6790236	Indicate the type of mutation identified while performing FH gene mutation analysis. ***Note: If the mutation type is not listed, proceed to Question 67a, otherwise, skip to Question 68.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
67a	Specify the other type of mutation	_____	6790245	Specify the type of mutation identified while performing FH gene mutation analysis.
68	Specify the FH mutation	_____	6820020	Specify the mutation that was identified while performing the FH gene mutation analysis.
69	Was FLCN mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6790139	Indicate whether or not an analysis for mutation in the FLCN gene was performed. ***Note: If FLCN mutation analysis was performed, proceed to Question 70, otherwise, skip to Question 73.***
70	Was a mutation in FLCN identified?	☐ Yes ☐ No	6790155	Indicate whether or not a mutation in the FLCN gene was identified. ***Note: If a mutation was identified, proceed to Question 71, otherwise, skip to Question 73.***
71	If a mutation was identified, indicate the type of mutation	☐ Frameshift insertion (specify) ☐ Frameshift deletion (specify) ☐ In-frame insertion (specify) ☐ In-frame deletion (specify) ☐ Nonsense (specify) ☐ Missense (specify) ☐ Splicing mutation (specify) ☐ Other (specify)	6790236	Indicate the type of mutation identified while performing FLCN gene mutation analysis. ***Note: If the mutation type is not listed, proceed to Question 71a, otherwise, skip to Question 72.***
71a	Specify the other type of mutation	_____	6790245	If not provided in the previous list, specify the type of mutation identified while performing FLCN gene mutation analysis.
72	Specify the FLCN mutation	_____	6815970	Specify the mutation that was identified while performing the FLCN gene mutation analysis.
73	Was TSC1 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6790140	Indicate whether or not an analysis for mutation in the TSC1 gene was performed. ***Note: If TSC1 mutation analysis was performed, proceed to Question 74, otherwise, skip to Question 77.***
74	Was a mutation in TSC1 identified?	☐ Yes ☐ No	6790156	Indicate whether or not a mutation in the TSC1 gene was identified. ***Note: If a mutation was identified, proceed to Question 75, otherwise, skip to Question 77.***
75	If a mutation was identified, indicate the type of mutation	☐ Frameshift insertion (specify) ☐ Frameshift deletion (specify) ☐ In-frame insertion (specify) ☐ In-frame deletion (specify) ☐ Nonsense (specify) ☐ Missense (specify) ☐ Splicing mutation (specify) ☐ Other (specify)	6790236	Indicate the type of mutation identified while performing TSC1 gene mutation analysis. ***Note: If the mutation type is not listed, proceed to Question 75a, otherwise, skip to Question 76.***
75a	Specify the other type of mutation	_____	6790245	If not provided in the previous list, specify the type of mutation identified while performing TSC1 gene mutation analysis.
76	Specify the TSC1 mutation	_____	6815971	Specify the mutation that was identified while performing the TSC1 gene mutation analysis.
77	Was TSC2 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6790141	Indicate whether or not an analysis for mutation in the TSC2 gene was performed. ***Note: If TSC2 mutation analysis was performed, proceed to Question 78, otherwise, skip to Question 81.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
78	Was a mutation in TSC2 identified?	☐ Yes ☐ No	6790157	Indicate whether or not a mutation in the TSC2 gene was identified. ***Note: If a mutation was identified, proceed to Question 79, otherwise, skip to Question 81.***
79	If a mutation was identified, indicate the type of mutation	☐ Frameshift insertion (specify) ☐ Frameshift deletion (specify) ☐ In-frame insertion (specify) ☐ In-frame deletion (specify) ☐ Nonsense (specify) ☐ Missense (specify) ☐ Splicing mutation (specify) ☐ Other (specify)	6790236	Indicate the type of mutation identified while performing TSC2 gene mutation analysis. ***Note: If the mutation type is not listed, proceed to Question 79a, otherwise, skip to Question 80.***
79a	Specify the other type of mutation	_____	6790245	If not provided in the previous list, specify the type of mutation identified while performing TSC2 gene mutation analysis.
80	Specify the TSC2 mutation	_____	6816066	Specify the germline mutation that was identified while performing the TSC2 gene mutation analysis.
81	Was PTEN mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063446	Indicate whether or not an analysis for mutation in the PTEN gene was performed. ***Note: If PTEN mutation analysis was performed, proceed to Question 82, otherwise, skip to Question 85.***
82	Was a mutation in PTEN identified?	☐ Yes ☐ No	6063529	Indicate whether or not a mutation in the PTEN gene was identified. ***Note: If a mutation was identified, proceed to Question 83, otherwise, skip to Question 85.***
83	If a mutation was identified, indicate the type of mutation	☐ Frameshift insertion (specify) ☐ Frameshift deletion (specify) ☐ In-frame insertion (specify) ☐ In-frame deletion (specify) ☐ Nonsense (specify) ☐ Missense (specify) ☐ Splicing mutation (specify) ☐ Other (specify)	6790236	Indicate the type of mutation identified while performing PTEN gene mutation analysis. ***Note: If the mutation type is not listed, proceed to Question 83a, otherwise, skip to Question 84.***
83a	Specify the other type of mutation	_____	6790245	If not provided in the previous list, specify the type of mutation identified while performing PTEN gene mutation analysis.
84	Specify the PTEN mutation	_____	6816076	Specify the mutation that was identified while performing the PTEN gene mutation analysis.
85	Was BAP-1 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6790142	Indicate whether or not an analysis for mutation in the BAP-1 gene was performed. ***Note: If BAP-1 mutation analysis was performed, proceed to Question 86, otherwise, skip to Question 89.***
86	Was a mutation in BAP-1 identified?	☐ Yes ☐ No	6790158	Indicate whether or not a mutation in the BAP-1 gene was identified. ***Note: If a mutation was identified, proceed to Question 87, otherwise, skip to Question 89.***
87	If a mutation was identified, indicate the type of mutation	☐ Frameshift insertion (specify) ☐ Frameshift deletion (specify) ☐ In-frame insertion (specify) ☐ In-frame deletion (specify) ☐ Nonsense (specify) ☐ Missense (specify) ☐ Splicing mutation (specify) ☐ Other (specify)	6790236	Indicate the type of mutation identified while performing BAP-1 gene mutation analysis. ***Note: If the mutation type is not listed, proceed to Question 87a, otherwise, skip to Question 88.***



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87a	Specify the other type of mutation	_____	6790245	Specify the type of mutation identified while performing BAP-1 gene mutation analysis.
88	Specify the BAP-1 mutation	_____	6816067	Specify the mutation that was identified while performing the BAP-1 gene mutation analysis.
89	Was SETD2 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6790143	Indicate whether or not an analysis for mutation in the SETD2 gene was performed. ***Note: If SETD2 mutation analysis was performed, proceed to Question 90, otherwise, skip to Question 93.***
90	Was a mutation in SETD2 identified?	☐ Yes ☐ No	6790159	Indicate whether or not a mutation in the SETD2 gene was identified. ***Note: If a mutation was identified, proceed to Question 91, otherwise, skip to Question 93.***
91	If a mutation was identified, indicate the type of mutation	☐ Frameshift insertion (specify) ☐ Frameshift deletion (specify) ☐ In-frame insertion (specify) ☐ In-frame deletion (specify) ☐ Nonsense (specify) ☐ Missense (specify) ☐ Splicing mutation (specify) ☐ Other (specify)	6790236	Indicate the type of mutation identified while performing SETD2 gene mutation analysis. ***Note: If the mutation type is not listed, proceed to Question 91a, otherwise, skip to Question 92.***
91a	Specify the other type of mutation	_____	6790245	If not provided in the previous list, specify the type of mutation identified while performing SETD2 gene mutation analysis.
92	Specify the SETD2 mutation	_____	6816068	Specify the mutation that was identified while performing the SETD2 gene mutation analysis.
93	Was PBRM1 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6790144	Indicate whether or not an analysis for mutation in the PBRM1 gene was performed. ***Note: If PBRM1 mutation analysis was performed, proceed to Question 94, otherwise, skip to Question 97.***
94	Was a mutation in PBRM1 identified?	☐ Yes ☐ No	6790160	Indicate whether or not a mutation in the PBRM1 gene was identified. ***Note: If a mutation was identified, proceed to Question 95, otherwise, skip to Question 97.***
95	If a mutation was identified, indicate the type of mutation	☐ Frameshift insertion (specify) ☐ Frameshift deletion (specify) ☐ In-frame insertion (specify) ☐ In-frame deletion (specify) ☐ Nonsense (specify) ☐ Missense (specify) ☐ Splicing mutation (specify) ☐ Other (specify)	6790236	Indicate the type of mutation identified while performing PBRM1 gene mutation analysis. ***Note: If the mutation type is not listed, proceed to Question 95a, otherwise, skip to Question 96.***
95a	Specify the other type of mutation	_____	6790245	If not provided in the previous list, specify the type of mutation identified while performing PBRM1 gene mutation analysis.
96	Specify the PBRM1 mutation	_____	6816069	Specify the mutation that was identified while performing the PBRM1 gene mutation analysis.
97	Was SDHB/C/D mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6790145	Indicate whether or not an analysis for mutation in the SDHB/C/D gene was performed. ***Note: If SDHB/C/D mutation analysis was performed, proceed to Question 98, otherwise, skip to Question 101.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
98	Was a mutation in SDHB identified?	☐ Yes ☐ No	6790161	Indicate whether or not a mutation in the SDHB gene was identified. ***Note: If a mutation was identified, proceed to Question 99, otherwise, skip to Question 101.***
99	If a mutation was identified, indicate the type of mutation	☐ Frameshift insertion (specify) ☐ Frameshift deletion (specify) ☐ In-frame insertion (specify) ☐ In-frame deletion (specify) ☐ Nonsense (specify) ☐ Missense (specify) ☐ Splicing mutation (specify) ☐ Other (specify)	6790236	Indicate the type of mutation identified while performing SDHB gene mutation analysis. ***Note: If the mutation type is not listed, proceed to Question 99a, otherwise, skip to Question 100.***
99a	Specify the other type of mutation	_____	6790245	If not provided in the previous list, specify the type of mutation identified while performing SDHB gene mutation analysis.
100	Specify the SDHB mutation	_____	6816070	Specify the mutation that was identified while performing the SDHB gene mutation analysis.
101	Was a mutation in SDHC identified?	☐ Yes ☐ No	6790162	Indicate whether or not a mutation in the SDHC gene was identified. ***Note: If a mutation was identified, proceed to Question 102, otherwise, skip to Question 104.***
102	If a mutation was identified, indicate the type of mutation	☐ Frameshift insertion (specify) ☐ Frameshift deletion (specify) ☐ In-frame insertion (specify) ☐ In-frame deletion (specify) ☐ Nonsense (specify) ☐ Missense (specify) ☐ Splicing mutation (specify) ☐ Other (specify)	6790236	Indicate the type of mutation identified while performing SDHC gene mutation analysis. ***Note: If the mutation type is not listed, proceed to Question 102a, otherwise, skip to Question 103.***
102a	Specify the other type of mutation	_____	6790245	If not provided in the previous list, specify the type of mutation identified while performing SDHC gene mutation analysis.
103	Specify the SDHC mutation	_____	6816074	Specify the mutation that was identified while performing the SDHC gene mutation analysis.
104	Was a mutation in SDHD identified?	☐ Yes ☐ No	6790163	Indicate whether or not a mutation in the SDHD gene was identified. ***Note: If a mutation was identified, proceed to Question 105, otherwise, skip to Question 107.***
105	If a mutation was identified, indicate the type of mutation	☐ Frameshift insertion (specify) ☐ Frameshift deletion (specify) ☐ In-frame insertion (specify) ☐ In-frame deletion (specify) ☐ Nonsense (specify) ☐ Missense (specify) ☐ Splicing mutation (specify) ☐ Other (specify)	6790236	Indicate the type of mutation identified while performing SDHD gene mutation analysis. ***Note: If the mutation type is not listed, proceed to Question 105a, otherwise, skip to Question 106.***
105a	Specify the other type of mutation	_____	6790245	If not provided in the previous list, specify the type of mutation identified while performing SDHD gene mutation analysis.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
106	Specify the SDHD mutation	_____	6816075	Specify the mutation that was identified while performing the SDHD gene mutation analysis.
107	Was MET mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6078874	Indicate whether or not an analysis for mutation in the MET gene was performed.
108	Was a mutation in MET identified?	☐ Yes ☐ No	6078886	Indicate whether or not a mutation in the MET gene was identified.
109	If MET mutation identified, which one?	☐ M1250T ☐ L1205V ☐ V1070G ☐ S1236R ☐ F1200I ☐ V1070E ☐ Y1230H ☐ H1094Y ☐ V504L ☐ Y1230C ☐ V1092I ☐ I639L ☐ D1228N ☐ V1070M ☐ Other (specify)	6078901	Select the mutation identified while performing MET gene mutation analysis.
109a	Specify the MET mutation	_____	6230525	If not provided in the previous list, specify the mutation identified while performing MET gene mutation analysis.
110	Was PD-L1 IHC performed?	☐ Yes ☐ No ☐ Unknown	6078873	Indicate whether immunohistochemical staining for PD-L1 was performed.
111	PD-L1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	4798631	Indicate the results of immunohistochemical staining for PD-L1.
Primary Tumor Sample Information				
112	Are you submitting a primary tumor tissue sample for this case?	☐ Yes ☐ No		***If yes, proceed to question 113.*** ***If submitting a metastatic/recurrent tumor biospecimen, proceed to Question 139.***
113	Primary tumor biospecimen ordinal	_____	6584265	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number should be "1".***
114	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
115	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
116	Sample represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this primary tumor specimen represent the PRIMARY DIAGNOSIS for this Case ID3? ***Note: If no, continue to Question 117, otherwise, skip to Question 118.***
117	Specify the ICD-10 code	_____	3226287	Provide the ICD-10 code for the primary tumor used to generate the model submitted to HCMI.
118	Tumor tissue sample preservation method	☐ Cryopreserved ☐ OCT ☐ FFPE ☐ Snap frozen ☐ Frozen	5432521	Provide the method used to preserve the tumor tissue sample collected for molecular characterization.
119	Anatomic site of tumor from which Model was Derived	☐ Kidney ☐ Lymph node ☐ Tumor thrombus ☐ Adrenal gland ☐ Other (specify)	4214629	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI. ***Note: If the tissue or organ not listed, proceed to Question 119a. Otherwise, skip to Question 120.***
119a	Other anatomic site from which the tumor was obtained	_____	5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
120	Method of cancer sample procurement	☐ Core needle biopsy ☐ Fine needle aspirate ☐ Incisional biopsy, wedge ☐ Partial nephrectomy ☐ Radical nephrectomy ☐ Total nephrectomy ☐ Other Method (specify)	3103514	Provide the procedure performed to obtain the primary tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 120a, otherwise, skip to Question 121.***
120a	Specify the other method of tumor sample procurement	_____	2006730	Specify the procedure performed to obtain the primary tumor tissue, if not included in the previous list.
121	Number of days from index date to date of tumor sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the tumor tissue submitted for HCMI.
122	Tumor tissue type	☐ Primary ☐ Additional Primary ☐ NOS	3288124	Provide the primary tumor tissue type for this sample.
Primary Tumor Model Information				
123	Primary model biospecimen ordinal	_____	6594596	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number is expected to be "1".***
124	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
125	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
126	Model represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this MODEL represent the PRIMARY DIAGNOSIS for this Case ID3?
127	Model's primary tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the PRIMARY TUMOR TISSUE from which this model is derived.
128	Model's primary tumor biospecimen ordinal	_____	6584265	Enter the biospecimen ordinal of the PRIMARY TUMOR TISSUE from which this model is derived.
Treatment Information				
129	History of neoadjuvant treatment	☐ No ☐ Yes; radiation prior to resection ☐ Yes; pharmaceutical treatment prior to resection ☐ Yes; both radiation and pharmaceutical treatment prior to resection ☐ Unknown	3382737	Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment. ***Note: Pharmaceutical therapy is addressed in Questions 130-136. Radiation therapy is addressed in Questions 137-138.***
130	Neoadjuvant chemotherapy type	☐ Cytotoxic chemotherapy ☐ Hormonal ☐ Immunotherapy (cellular and immune checkpoint) ☐ Targeted therapy (small molecule inhibitors and targeted antibodies) ☐ Not applicable	5832928	Select all neoadjuvant chemotherapy types that were administered to the patient. ***Note: Cytotoxic chemotherapy is addressed in Questions 131-132. Immunotherapy is addressed in Questions 133-134. Targeted therapy is addressed in Questions 135-136.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
131	Neoadjuvant chemotherapeutic regimen	☐ Sunitinib ☐ Other (specify)	2853313	Select all chemotherapeutics used for neoadjuvant therapy. ***Note: If neoadjuvant chemotherapy was not given, skip to Question 133. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 131a, otherwise, skip to Question 132.***
131a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapies administered.
132	Days to neoadjuvant chemotherapy treatment from index date	_____	5102411	Provide the number of days from index date to the date of treatment with neoadjuvant chemotherapy.
133	Immunotherapy	☐ Nivolumab/Ipilimumab ☐ Nivolumab ☐ Pembrolizumab and Axitinib ☐ Pembrolizumab ☐ Bevacizumab and interferon ☐ Interferon ☐ IL-2 ☐ Other (specify)	6790106	Select the immunotherapy administered to the patient. ***Note: If immunotherapy was not administered, skip to Question 135. If the immunotherapy is not listed, proceed to Question 133a, otherwise, skip to Question 134.***
133a	Specify other immunotherapy	_____	2185614	If not provided in the previous list, specify the name of the immunotherapy administered to the patient.
134	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
135	Targeted Therapy	☐ Sunitinib ☐ Pazopanib ☐ Temsirolimus ☐ Everolimus ☐ Lenvatinib and Everolimus ☐ Lenvatinib ☐ Cabozantinib ☐ Sorafenib ☐ Axitinib ☐ Bevacizumab ☐ Other (specify)	6790102	Select the targeted therapy administered to the patient. ***Note: If targeted therapy was not administered, skip to Question 137. If the targeted therapy regimen is not listed, proceed to Question 135a, otherwise, skip to Question 136.***
135a	Specify targeted therapy	_____	4308476	Provide the name of the targeted therapy administered to the patient.
136	Days to targeted therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with targeted therapy.
137	Radiation therapy administered type	☐ 2D conventional ☐ 3D conformal ☐ Brachytherapy HDR ☐ Brachytherapy LDR ☐ IMRT ☐ Proton Beam ☐ Stereotactic Body RT ☐ Stereotactic Radiosurgery ☐ WBRT ☐ Other (specify) ☐ Unspecified ☐ Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. ***Note: If radiation therapy was not administered, proceed to Question 139. If the radiation therapy is not listed, proceed to Question 137a, otherwise, skip to Question 138.***
137a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
138	Days to radiation treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with radiation therapy.
Metastatic/Recurrent Tumor Biospecimen Information				
139	Are you submitting a metastatic/recurrent tumor tissue sample?	☐ Yes ☐ No		Indicate whether a metastatic/recurrent tumor biospecimen was collected for this ID3 case. ***Note: If yes, proceed to Question 140. If submitting an OTHER tissue sample, proceed to Question 243.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
140	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1", the second should be number "2", etc.***
141	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
142	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
143	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
144	Number of days from index date to date of diagnosis of metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic/recurrent disease.
145	Method of metastatic/ recurrent cancer sample procurement	☐ Core needle biopsy ☐ Fine needle aspirate ☐ Metastasectomy ☐ Lymph node dissection ☐ Incisional biopsy, wedge ☐ Other method (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 145a, otherwise, skip to Question 146.***
145a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
146	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
147	Metastatic/recurrent site	☐ Kidney ☐ Pelvis ☐ Ureter ☐ Adrenal gland, contralateral ☐ Adrenal gland, ipsilateral ☐ Pancreas ☐ Lymph node(s) ☐ Brain ☐ Liver ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 147a, otherwise, skip to Question 148.***
147a	Other metastatic/ recurrent site	_____	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
148	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
149	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
150	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
151	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
152	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
153	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
154	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
155	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
Prognostic/Predictive/Lifestyle Features for Metastatic/Recurrent Tumor Prognosis or Responsiveness to Treatment				
156	Sarcomatoid features	☐ Yes, value available (specify) ☐ Yes, value not specified ☐ Not identified	5334382	Indicate whether histologic features of a sarcomatous component (pattern of dedifferentiation) were present in the primary tumor. ***Note: if the percentage of sarcomatoid features is known, proceed to Question 156a, otherwise, skip to Question 157.***
156a	If sarcomatoid features are present, indicate the percentage	_____%	6790124	Specify the percentage of the sarcomatoid features present in the patient's cancer.
157	Rhabdoid features	☐ Yes, value available (specify) ☐ Yes, value not specified ☐ Not identified	6790118	Indicate whether histologic features of a rhabdoid component were present in the primary tumor. ***Note: if the percentage of rhabdoid features is known, proceed to Question 157a, otherwise, skip to Question 158.***
157a	If rhabdoid features are present, indicate the percentage	_____%	6790119	Specify the percentage of the rhabdoid features present in the patient's cancer.
158	Tumor necrosis	☐ Yes, value available (specify) ☐ Yes, value not specified ☐ Not identified	6790121	Indicate whether histologic features of necrosis were present in the primary tumor. ***Note: if the percentage of necrotic features is known, proceed to Question 158a, otherwise, skip to Question 159.***
158a	If tumor necrosis is present, indicate the percentage	_____%	6790122	Specify the percentage of necrosis present in the patient's cancer.
159	Lymphovascular invasion	☐ Present ☐ Absent ☐ Cannot be determined	64727	Indicate if large vessel (vascular) invasion or small, thin-walled (lymphatic) invasion was detected in a tumor specimen.
Metastatic/Recurrent Tumor Clinical Molecular Characterization ***(Note: Questions 160-211 may be repeated for additional metastatic/recurrent biospecimens.)***				
160	Was VHL mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6790137	Indicate whether or not an analysis for mutation in the VHL gene was performed. ***Note: If VHL mutation analysis was performed, proceed to Question 161, otherwise, skip to Question 165.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
161	Was a germline mutation in VHL identified?	☐ Yes ☐ No	6790146	Indicate whether or not a mutation in the VHL gene was identified. ***Note: If a mutation was identified, proceed to Question 162, otherwise, skip to Question 165.***
162	If a mutation was identified, indicate the type of mutation	☐ Frameshift insertion (specify) ☐ Frameshift deletion (specify) ☐ In-frame insertion (specify) ☐ In-frame deletion (specify) ☐ Nonsense (specify) ☐ Missense (specify) ☐ Splicing mutation (specify) ☐ Other (specify)	6790236	Indicate the type of mutation identified while performing VHL gene mutation analysis. ***Note: If the mutation type is not listed, proceed to Question 162a, otherwise, skip to Question 163.***
162a	Specify the other type of mutation	_____	6790245	If not provided in the previous list, specify the type of mutation identified while performing VHL gene mutation analysis.
163	Specify the VHL mutation	_____	6790147	Specify the germline mutation that was identified while performing the VHL gene mutation analysis.
164	Mutation identification method	☐ Next generation targeted sequencing ☐ Whole exome sequencing ☐ Not performed ☐ Other (specify)	6003729	Indicate the method that was used to perform VHL gene mutation analysis. ***Note: If the mutation identification method is not listed, proceed to Question 164a, otherwise, skip to Question 165.***
164a	Specify other mutation identification method	_____	6002204	If not provided in the previous list, specify the method that was used to perform VHL gene mutation analysis.
165	Was FH mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6790138	Indicate whether or not an analysis for mutation in the FH gene was performed. ***Note: If FH mutation analysis was performed, proceed to Question 166, otherwise, skip to Question 169.***
166	Was a mutation in FH identified?	☐ Yes ☐ No	6790148	Indicate whether or not a mutation in the FH gene was identified. ***Note: If a mutation was identified, proceed to Question 167, otherwise, skip to Question 169.***
167	If a mutation was identified, indicate the type of mutation	☐ Frameshift insertion (specify) ☐ Frameshift deletion (specify) ☐ In-frame insertion (specify) ☐ In-frame deletion (specify) ☐ Nonsense (specify) ☐ Missense (specify) ☐ Splicing mutation (specify) ☐ Other (specify)	6790236	Indicate the type of mutation identified while performing FH gene mutation analysis. ***Note: If the mutation type is not listed, proceed to Question 167a, otherwise, skip to Question 168.***
167a	Specify the other type of mutation	_____	6790245	Specify the type of mutation identified while performing VHL gene mutation analysis.
168	Specify the FH mutation	_____	6820020	Specify the mutation that was identified while performing the FH gene mutation analysis.
169	Was FLCN mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6790139	Indicate whether or not an analysis for mutation in the FLCN gene was performed. ***Note: If FLCN mutation analysis was performed, proceed to Question 170, otherwise, skip to Question 173.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
170	Was a mutation in FLCN identified?	☐ Yes ☐ No	6790155	Indicate whether or not a mutation in the FLCN gene was identified. ***Note: If a mutation was identified, proceed to Question 171, otherwise, skip to Question 173.***
171	If a mutation was identified, indicate the type of mutation	☐ Frameshift insertion (specify) ☐ Frameshift deletion (specify) ☐ In-frame insertion (specify) ☐ In-frame deletion (specify) ☐ Nonsense (specify) ☐ Missense (specify) ☐ Splicing mutation (specify) ☐ Other (specify)	6790236	Indicate the type of mutation identified while performing FLCN gene mutation analysis. ***Note: If the mutation type is not listed, proceed to Question 171a, otherwise, skip to Question 172.***
171a	Specify the other type of mutation	_____	6790245	If not provided in the previous list, specify the type of mutation identified while performing FLCN gene mutation analysis.
172	Specify the FLCN mutation	_____	6815970	Specify the mutation that was identified while performing the FLCN gene mutation analysis.
173	Was TSC1 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6790140	Indicate whether or not an analysis for mutation in the TSC1 gene was performed. ***Note: If TSC1 mutation analysis was performed, proceed to Question 174, otherwise, skip to Question 177.***
174	Was a mutation in TSC1 identified?	☐ Yes ☐ No	6790156	Indicate whether or not a mutation in the TSC1 gene was identified. ***Note: If a mutation was identified, proceed to Question 175, otherwise, skip to Question 177.***
175	If a mutation was identified, indicate the type of mutation	☐ Frameshift insertion (specify) ☐ Frameshift deletion (specify) ☐ In-frame insertion (specify) ☐ In-frame deletion (specify) ☐ Nonsense (specify) ☐ Missense (specify) ☐ Splicing mutation (specify) ☐ Other (specify)	6790236	Indicate the type of mutation identified while performing TSC1 gene mutation analysis. ***Note: If the mutation type is not listed, proceed to Question 175a, otherwise, skip to Question 176.***
175a	Specify the other type of mutation	_____	6790245	If not provided in the previous list, specify the type of mutation identified while performing TSC1 gene mutation analysis.
176	Specify the TSC1 mutation	_____	6815971	Specify the mutation that was identified while performing the TSC1 gene mutation analysis.
177	Was TSC2 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6790141	Indicate whether or not an analysis for mutation in the TSC2 gene was performed. ***Note: If TSC2 mutation analysis was performed, proceed to Question 178, otherwise, skip to Question 181.***
178	Was a mutation in TSC2 identified?	☐ Yes ☐ No	6790157	Indicate whether or not a mutation in the TSC2 gene was identified. ***Note: If a mutation was identified, proceed to Question 179, otherwise, skip to Question 181.***
179	If a mutation was identified, indicate the type of mutation	☐ Frameshift insertion (specify) ☐ Frameshift deletion (specify) ☐ In-frame insertion (specify) ☐ In-frame deletion (specify) ☐ Nonsense (specify)	6790236	Indicate the type of mutation identified while performing TSC2 gene mutation analysis. ***Note: If the mutation type is not listed, proceed to Question 179a, otherwise, skip to Question 180.***



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		☐ Missense (specify) ☐ Splicing mutation (specify) ☐ Other (specify)		
179a	Specify the other type of mutation	_____	6790245	If not provided in the previous list, specify the type of mutation identified while performing TSC2 gene mutation analysis.
180	Specify the TSC2 mutation	_____	6816066	Specify the germline mutation that was identified while performing the TSC2 gene mutation analysis.
181	Was PTEN mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063446	Indicate whether or not an analysis for mutation in the PTEN gene was performed. ***Note: If PTEN mutation analysis was performed, proceed to Question 182, otherwise, skip to Question 185.***
182	Was a mutation in PTEN identified?	☐ Yes ☐ No	6063529	Indicate whether or not a mutation in the PTEN gene was identified. ***Note: If a mutation was identified, proceed to Question 183, otherwise, skip to Question 185.***
183	If a mutation was identified, indicate the type of mutation	☐ Frameshift insertion (specify) ☐ Frameshift deletion (specify) ☐ In-frame insertion (specify) ☐ In-frame deletion (specify) ☐ Nonsense (specify) ☐ Missense (specify) ☐ Splicing mutation (specify) ☐ Other (specify)	6790236	Indicate the type of mutation identified while performing PTEN gene mutation analysis. ***Note: If the mutation type is not listed, proceed to Question 183a, otherwise, skip to Question 184.***
183a	Specify the other type of mutation	_____	6790245	If not provided in the previous list, specify the type of mutation identified while performing PTEN gene mutation analysis.
184	Specify the PTEN mutation	_____	6816076	Specify the mutation that was identified while performing the PTEN gene mutation analysis.
185	Was BAP-1 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6790142	Indicate whether or not an analysis for mutation in the BAP-1 gene was performed. ***Note: If BAP-1 mutation analysis was performed, proceed to Question 186, otherwise, skip to Question 189.***
186	Was a mutation in BAP-1 identified?	☐ Yes ☐ No	6790158	Indicate whether or not a mutation in the BAP-1 gene was identified. ***Note: If a mutation was identified, proceed to Question 187, otherwise, skip to Question 189.***
187	If a mutation was identified, indicate the type of mutation	☐ Frameshift insertion (specify) ☐ Frameshift deletion (specify) ☐ In-frame insertion (specify) ☐ In-frame deletion (specify) ☐ Nonsense (specify) ☐ Missense (specify) ☐ Splicing mutation (specify) ☐ Other (specify)	6790236	Indicate the type of mutation identified while performing BAP-1 gene mutation analysis. ***Note: If the mutation type is not listed, proceed to Question 187a, otherwise, skip to Question 188.***
187a	Specify the other type of mutation	_____	6790245	Specify the type of mutation identified while performing BAP-1 gene mutation analysis.
188	Specify the BAP-1 mutation	_____	6816067	Specify the mutation that was identified while performing the BAP-1 gene mutation analysis.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
189	Was SETD2 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6790143	Indicate whether or not an analysis for mutation in the SETD2 gene was performed. ***Note: If SETD2 mutation analysis was performed, proceed to Question 190, otherwise, skip to Question 193.***
190	Was a mutation in SETD2 identified?	☐ Yes ☐ No	6790159	Indicate whether or not a mutation in the SETD2 gene was identified. ***Note: If a mutation was identified, proceed to Question 191, otherwise, skip to Question 193.***
191	If a mutation was identified, indicate the type of mutation	☐ Frameshift insertion (specify) ☐ Frameshift deletion (specify) ☐ In-frame insertion (specify) ☐ In-frame deletion (specify) ☐ Nonsense (specify) ☐ Missense (specify) ☐ Splicing mutation (specify) ☐ Other (specify)	6790236	Indicate the type of mutation identified while performing SETD2 gene mutation analysis. ***Note: If the mutation type is not listed, proceed to Question 191a, otherwise, skip to Question 192.***
191a	Specify the other type of mutation	_____	6790245	If not provided in the previous list, specify the type of mutation identified while performing SETD2 gene mutation analysis.
192	Specify the SETD2 mutation	_____	6816068	Specify the mutation that was identified while performing the SETD2 gene mutation analysis.
193	Was PBRM1 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6790144	Indicate whether or not an analysis for mutation in the PBRM1 gene was performed. ***Note: If PBRM1 mutation analysis was performed, proceed to Question 194, otherwise, skip to Question 197.***
194	Was a mutation in PBRM1 identified?	☐ Yes ☐ No	6790160	Indicate whether or not a mutation in the PBRM1 gene was identified. ***Note: If a mutation was identified, proceed to Question 195, otherwise, skip to Question 197.***
195	If a mutation was identified, indicate the type of mutation	☐ Frameshift insertion (specify) ☐ Frameshift deletion (specify) ☐ In-frame insertion (specify) ☐ In-frame deletion (specify) ☐ Nonsense (specify) ☐ Missense (specify) ☐ Splicing mutation (specify) ☐ Other (specify)	6790236	Indicate the type of mutation identified while performing PBRM1 gene mutation analysis. ***Note: If the mutation type is not listed, proceed to Question 195a, otherwise, skip to Question 196.***
195a	Specify the other type of mutation	_____	6790245	If not provided in the previous list, specify the type of mutation identified while performing PBRM1 gene mutation analysis.
196	Specify the PBRM1 mutation	_____	6816069	Specify the mutation that was identified while performing the PBRM1 gene mutation analysis.
197	Was SDHB/C/D mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6790145	Indicate whether or not an analysis for mutation in the SDHB/C/D gene was performed. ***Note: If SDHB/C/D mutation analysis was performed, proceed to Question 198, otherwise, skip to Question 201.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
198	Was a mutation in SDHB identified?	☐ Yes ☐ No	6790161	Indicate whether or not a mutation in the SDHB gene was identified. ***Note: If a mutation was identified, proceed to Question 199, otherwise, skip to Question 201.***
199	If a mutation was identified, indicate the type of mutation	☐ Frameshift insertion (specify) ☐ Frameshift deletion (specify) ☐ In-frame insertion (specify) ☐ In-frame deletion (specify) ☐ Nonsense (specify) ☐ Missense (specify) ☐ Splicing mutation (specify) ☐ Other (specify)	6790236	Indicate the type of mutation identified while performing SDHB gene mutation analysis. ***Note: If the mutation type is not listed, proceed to Question 199a, otherwise, skip to Question 200.***
199a	Specify the other type of mutation	_____	6790245	If not provided in the previous list, specify the type of mutation identified while performing SDHB gene mutation analysis.
200	Specify the SDHB mutation	_____	6816070	Specify the mutation that was identified while performing the SDHB gene mutation analysis.
201	Was a mutation in SDHC identified?	☐ Yes ☐ No	6790162	Indicate whether or not a mutation in the SDHC gene was identified. ***Note: If a mutation was identified, proceed to Question 202, otherwise, skip to Question 204.***
202	If a mutation was identified, indicate the type of mutation	☐ Frameshift insertion (specify) ☐ Frameshift deletion (specify) ☐ In-frame insertion (specify) ☐ In-frame deletion (specify) ☐ Nonsense (specify) ☐ Missense (specify) ☐ Splicing mutation (specify) ☐ Other (specify)	6790236	Indicate the type of mutation identified while performing SDHC gene mutation analysis. ***Note: If the mutation type is not listed, proceed to Question 202a, otherwise, skip to Question 203.***
202a	Specify the other type of mutation	_____	6790245	If not provided in the previous list, specify the type of mutation identified while performing SDHC gene mutation analysis.
203	Specify the SDHC mutation	_____	6816074	Specify the mutation that was identified while performing the SDHC gene mutation analysis.
204	Was a mutation in SDHD identified?	☐ Yes ☐ No	6790163	Indicate whether or not a mutation in the SDHD gene was identified. ***Note: If a mutation was identified, proceed to Question 205, otherwise, skip to Question 207.***
205	If a mutation was identified, indicate the type of mutation	☐ Frameshift insertion (specify) ☐ Frameshift deletion (specify) ☐ In-frame insertion (specify) ☐ In-frame deletion (specify) ☐ Nonsense (specify) ☐ Missense (specify) ☐ Splicing mutation (specify) ☐ Other (specify)	6790236	Indicate the type of mutation identified while performing SDHD gene mutation analysis. ***Note: If the mutation type is not listed, proceed to Question 205a, otherwise, skip to Question 206.***
205a	Specify the other type of mutation	_____	6790245	If not provided in the previous list, specify the type of mutation identified while performing SDHD gene mutation analysis.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
206	Specify the SDHD mutation	_____	6816075	Specify the mutation that was identified while performing the SDHD gene mutation analysis.
207	Was MET mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6078874	Indicate whether or not an analysis for mutation in the MET gene was performed.
208	Was a mutation in MET identified?	☐ Yes ☐ No	6078886	Indicate whether or not a mutation in the MET gene was identified.
209	If MET mutation identified, which one?	☐ M1250T ☐ L1205V ☐ V1070G ☐ S1236R ☐ F1200I ☐ V1070E ☐ Y1230H ☐ H1094Y ☐ V504L ☐ Y1230C ☐ V1092I ☐ I639L ☐ D1228N ☐ V1070M ☐ Other (specify)	6078901	Select the mutation identified while performing MET gene mutation analysis.
209a	Specify the MET mutation	_____	6230525	If not provided in the previous list, specify the mutation identified while performing MET gene mutation analysis.
210	Was PD-L1 IHC performed?	☐ Yes ☐ No ☐ Unknown	6078873	Indicate whether immunohistochemical staining for PD-L1 was performed.
211	PD-L1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	4798631	Indicate the results of immunohistochemical staining for PD-L1.
Additional Metastatic/Recurrent Tumor Biospecimen Information (if applicable)				
212	Are you submitting an additional metastatic/ recurrent tumor tissue sample?	☐ Yes ☐ No		A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen. ***Note: If yes, proceed to Question 213, otherwise, skip to Question 233.***
213	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. The first biospecimen should be number "1," the second should be number "2," etc.
214	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
215	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
216	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
217	Number of days from index date to date of diagnosis of additional metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of additional metastatic/recurrent disease.



Enrollment: Kidney

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
218	Method of metastatic/ recurrent cancer sample procurement	☐ Core needle biopsy ☐ Fine needle aspirate ☐ Metastasectomy ☐ Lymph node dissection ☐ Incisional biopsy, wedge ☐ Other (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 218a, otherwise, skip to Question 219.***
218a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
219	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
220	Metastatic/ recurrent site	☐ Kidney ☐ Pelvis ☐ Ureter ☐ Adrenal gland, contralateral ☐ Adrenal gland, ipsilateral ☐ Pancreas ☐ Lymph node(s) ☐ Brain ☐ Liver ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 220a, otherwise, skip to Question 221.***
220a	Other metastatic/ recurrent site	_____	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
221	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
222	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
223	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
224	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
225	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
226	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
227	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
228	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.



Enrollment: Kidney

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Prognostic/Predictive/Lifestyle Features for Additional Metastatic/Recurrent Tumor Prognosis or Responsiveness to Treatment				
229	Sarcomatoid features	☐ Yes, value available (specify) ☐ Yes, value not specified ☐ Not identified	5334382	Indicate whether histologic features of a sarcomatous component (pattern of dedifferentiation) were present in the primary tumor. ***Note: if the percentage of sarcomatoid features is known, proceed to Question 229a, otherwise, skip to Question 230.***
229a	If sarcomatoid features are present, indicate the percentage	_____%	6790124	Specify the percentage of the sarcomatoid features present in the patient's cancer.
230	Rhabdoid features	☐ Yes, value available (specify) ☐ Yes, value not specified ☐ Not identified	6790118	Indicate whether histologic features of a rhabdoid component were present in the primary tumor. ***Note: if the percentage of rhabdoid features is known, proceed to Question 230a, otherwise, skip to Question 231.***
230a	If rhabdoid features are present, indicate the percentage	_____%	6790119	Specify the percentage of the rhabdoid features present in the patient's cancer.
231	Tumor necrosis	☐ Yes, value available (specify) ☐ Yes, value not specified ☐ Not identified	6790121	Indicate whether histologic features of necrosis were present in the primary tumor. ***Note: if the percentage of necrotic features is known, proceed to Question 231a, otherwise, skip to Question 232.***
231a	If tumor necrosis is present, indicate the percentage	_____%	6790122	Specify the percentage of necrosis present in the patient's cancer.
232	Lymphovascular invasion	☐ Present ☐ Absent ☐ Cannot be determined	64727	Indicate if large vessel (vascular) invasion or small, thin-walled (lymphatic) invasion was detected in a tumor specimen.
Additional Metastatic/Recurrent Tumor Clinical Molecular Characterization ***(Note: Questions 160-211 may be repeated to capture clinical molecular characterization information for additional metastatic/recurrent biospecimens.)***				
Metastatic/Recurrent Tumor Model Information				
233	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
234	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
235	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
236	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
237	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.



Enrollment: Kidney

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Additional Metastatic/Recurrent Biospecimen Tumor Model Information (if applicable)				
238	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
239	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
240	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
241	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
242	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Other Biospecimen Information				
243	Are you submitting an OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an OTHER tissue sample (e.g. pre-malignant, non-malignant, or dysplastic tissue, etc.) was collected for HCMI for this case. ***Note: If yes, proceed to Question 244.***
244	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
245	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
246	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
247	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
248	Other method of cancer sample procurement	☐ Core needle biopsy ☐ Fine needle aspirate ☐ Lymph node dissection ☐ Incisional biopsy, wedge ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 248a, otherwise, skip to Question 249.***
248a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
249	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
250	Tissue type	☐ Pre-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 250a, otherwise, skip to Question 251.***



Enrollment: Kidney

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
250a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
251	Anatomic site of OTHER tissue	☐ Kidney ☐ Ureter ☐ Adrenal gland ☐ Pelvis ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 251a, otherwise, skip to Question 252.***
251a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.
252	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
253	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Additional OTHER biospecimen Information (if applicable)				
254	Are you submitting an additional OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an additional OTHER tissue sample (pre-malignant, non-malignant, or dysplastic tissue, etc.) is being submitted for HCMI for this case. ***Note: If yes, proceed to Question 255, otherwise, skip to Question 265.***
255	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
256	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
257	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
258	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
259	Other method of cancer sample procurement	☐ Core needle biopsy ☐ Fine needle aspirate ☐ Lymph node dissection ☐ Incisional biopsy, wedge ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 259a, otherwise, skip to Question 260.***
259a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
260	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
261	Tissue type	☐ Pre-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 261a, otherwise, skip to Question 262.***
261a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.



Enrollment: Kidney

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
262	Anatomic site of OTHER tissue	☐ Kidney ☐ Ureter ☐ Adrenal gland ☐ Pelvis ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 262a, otherwise, skip to Question 263.***
262a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.
263	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
264	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Other Tissue Model Information				
265	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
266	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
267	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
268	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
269	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.
Additional Other Tissue Model Information (if applicable)				
270	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
271	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
272	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
273	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
274	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.



Enrollment: Lung

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Form Notes: An Enrollment Form should be completed for each HCMI case upon qualification notice from Leidos. All information provided on this form should include activity from the Date of Initial Pathologic Diagnosis to the most recent Date of Last Contact with the patient.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	☐ Initial pathologic diagnosis ☐ Sample procurement ☐ First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.
Patient Information				
4	Gender	☐ Male ☐ Female ☐ Unspecified	2200604	Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
5	Height	_____	649	Provide the patient's height, in centimeters.
6	Weight	_____	651	Provide the patient's weight, in kilograms.
7	Body mass index (BMI)	_____	2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
8	Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown ☐ Not reported	2192199	Provide the patient's race using the defined categories. **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 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. **Black or African American:** A person having origins in any of the black racial groups of Africa. **Native Hawaiian or other Pacific Islander:** A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island. **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
9	Ethnicity	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Not reported	2192217	Provide the patient's ethnicity using the defined categories. **Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. **Not Hispanic or Latino:** A person not meeting the definition of Hispanic or Latino.
10	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.



Enrollment: Lung

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
10	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.
11	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. ***Note: If the patient's age is greater than 32,872 days (90 years), please enter 32,872.***
12	Year of birth	_____	2896954	Provide the year of the patient's birth. If the patient was born prior to 1928, insert the date 1928.
13	Family history of cancer	☐ Same ☐ Different ☐ None ☐ Unknown	5832923	Has a first-degree relative of the patient been diagnosed with a cancer of the same or a different type?
14	Smoking history	☐ Lifelong non-smoker (<100 cigarettes smoked in a lifetime) ☐ Current smoker (includes daily and non-daily smokers) ☐ Current reformed smoker (duration not specified) ☐ Current reformed smoker for >15 years ☐ Current reformed smoker for ≤15 years	2181650	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories.
15	Number pack years smoked	_____	2955385	Indicate the number of pack years smoked. ***Note: Numeric computed value to represent lifetime tobacco exposure defined as number of cigarettes smoked per day x number of years smoked divided by 20.***
16	Tobacco smoking quit year	_____	2228610	Indicate the year in which the patient quit smoking.
17	Asbestos exposure?	☐ Yes ☐ No ☐ Unknown	1253	Indicate whether the patient has been exposed to asbestos.
18	Radon exposure?	☐ Yes ☐ No ☐ Unknown	2816352	Indicate whether the patient has been exposed to radon.
19	Metastasis at diagnosis assessment status	☐ Metastatic ☐ Non-metastatic (confirmed) ☐ Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor. ***Note: If metastatic at diagnosis, proceed to Question 20, otherwise, skip to Question 21.***
20	Metastatic site(s) at diagnosis	☐ Adrenal gland ☐ Bone ☐ Brain ☐ Liver ☐ Lung ☐ Lymph node(s)- non-regional ☐ Other (specify)	3108271	Indicate the site(s) of metastasis at the time of diagnosis of the primary tumor. ***Note: If the anatomic site of metastasis is not listed, proceed to Question 20a, otherwise, skip to Question 21.***
20a	Specify metastatic site(s)	_____	3128033	If the site of metastasis is not included on the provided list, specify the site of metastasis.
Biospecimen Information				
21	Tissue sample type(s) collected for HCMI for this case	☐ Normal tissue ☐ Primary tumor ☐ Metastatic ☐ Recurrent ☐ Other tissue	2006911	Please select all the tissue sample types submitted for HCMI with this case.



Enrollment: Lung

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
22	Number of NORMAL tissues biospecimens collected for HCMI for this case	_____	6584256	Please provide the number of normal tissue specimens obtained for HCMI for this case. ***Note: This number is expected to be 1.***
23	Number of PRIMARY cancer tissue biospecimens collected for HCMI model development for this case	_____	6584257	Please provide the number of primary tumor specimens obtained for HCMI for this case. ***Note: A single primary tumor biospecimen obtained that is portioned for both sequencing and model generation counts as 1 single primary tumor specimen. This number is expected to be 1.***
24	Number of METASTATIC/ RECURRENT cancer tissue biospecimens collected for HCMI model development for this case	_____	6584258	Please provide the number of metastatic and/or recurrent cancer biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
25	Number of OTHER tissue biospecimens collected for HCMI model development for this case	_____	6584259	Please provide the number of pre-malignant, non-malignant, or dysplastic tissue biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
26	Total number of tissue biospecimens collected for HCMI for this case	_____	6584271	Please provide the total number of tissue biospecimens collected for HCMI for this case. ***Note: This number should be the sum of the normal, primary tumor, metastatic/recurrent tumor, and other biospecimen counts above.***
Normal Control Information				
27	Normal tissue biospecimen ordinal	_____	6584264	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
28	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
29	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
30	Type of normal control	☐ Whole blood ☐ Buccal cells ☐ Buffy coat ☐ Lymphocytes ☐ Extracted DNA from blood ☐ Extracted DNA from saliva ☐ Extracted DNA from buccal cells ☐ Extracted DNA from normal tissue ☐ FFPE non-neoplastic tissue ☐ Non-neoplastic tissue	3081936	Indicate the type of normal control submitted for this case.



Enrollment: Lung

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	☐ Data Entry Options	CDE ID	Instruction Text
31	Anatomic site of normal tissue	☐ Bronchus ☐ Left lower lobe lung ☐ Left upper lobe lung ☐ Right lower lobe lung ☐ Right middle lobe lung ☐ Right upper lobe lung ☐ Other (specify) ☐ Not applicable	4132152	If non-neoplastic tissue was submitted as the normal control, select the anatomic site of the normal tissue. ***Note: If the anatomic site of normal tissue is not listed, proceed to Question 31a, otherwise, skip to Question 32.***
31a	Other anatomic site of normal tissue	_____	3288189	If non-neoplastic tissue, adjacent tissue, or normal tissue from another anatomic site was submitted as the normal control, provide the anatomic site of the normal tissue.
32	Distance from tumor to normal control tissue (if not blood)	☐ Adjacent (< or = 2cm) ☐ Distal (>2cm) ☐ Unknown ☐ Not applicable	3088708	Indicate the distance from the site of normal tumor collection to the primary tumor. ***Note: If normal tissue was not submitted, select 'Not applicable'.***
33	Normal tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the normal tissue sample collected for molecular characterization.
Primary Tumor Biospecimen Information				
34	ICD-10 code for primary tumor	☐ C34.0 ☐ C34.1 ☐ C34.2 ☐ C34.3 ☐ C34.8 ☐ C34.9 ☐ Other (specify)	3226287	Provide the ICD-10 code for the primary tumor as used to generate the ID3 for this subject. ***Note: If the ICD-10 code is not listed, proceed to 34a, otherwise, skip to Question 35.***
34a	Other ICD-10 code for primary tumor	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.
35	Tumor morphology	☐ 8052/3 ☐ 8070/3 ☐ 8073/3 ☐ 8083/3 ☐ 8084/3 ☐ 8140/3 ☐ 8230/3 ☐ 8250/3 ☐ 8255/3 ☐ 8260/3 ☐ 8490/3 ☐ 8550/3 ☐ 8560/3 ☐ Other (specify)	3226275	Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor. ***Note: If the ICD-O-3 histology code of the primary tumor is not listed, proceed to Question 35a, otherwise, skip to Question 36.***
35a	Specify other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.
36	Tissue or organ of origin	☐ Lung ☐ Other (specify)	3427536	Using the patient's pathology/laboratory report, select the primary site of the disease. ***Note: If the primary site of the disease is not listed, proceed to Question 36a, otherwise skip to Question 37.***
36a	Other tissue or organ of origin	_____	5946219	If the primary site of the disease is not included on the previous list, provide the primary site of the disease.
37	Histological Type	☐ Lung cancer ☐ Other (specify)	3081932	Select the surgical pathology text description of the histological tumor type. ***Note: If the histological tumor type is not listed, proceed to Question 37a, otherwise, skip to Question 38.***
37a	Other histological type	_____	3294805	If the traditional surgical pathology text description of the histological tumor type is not included on the previous list, please specify the histological type.



Enrollment: Lung

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
38	Histological subtype	☐ Acinar adenocarcinoma ☐ Adenocarcinoma in situ; mucinous ☐ Adenocarcinoma in situ; nonmucinous ☐ Adenosquamous carcinoma ☐ Basaloid squamous cell carcinoma ☐ Colloid adenocarcinoma ☐ Enteric adenocarcinoma ☐ Fetal adenocarcinoma ☐ Keratinizing squamous cell carcinoma ☐ Lepidic adenocarcinoma ☐ Micropapillary adenocarcinoma ☐ Minimally invasive adenocarcinoma; mucinous ☐ Minimally invasive adenocarcinoma; nonmucinous ☐ Nonkeratinizing squamous cell carcinoma ☐ Papillary adenocarcinoma ☐ Signet ring adenocarcinoma ☐ Solid adenocarcinoma ☐ Adenocarcinoma (NOS) ☐ Squamous cell carcinoma (NOS) ☐ Other (specify) ☐ Unknown	3081934	Using the patient's pathology/laboratory report, select the histological subtype of the primary tumor. ***Note: If the histological subtype is not listed, proceed to Question 38a, otherwise, skip to Question 39.***
38a	Other histological subtype	_____	3124492	If the histological subtype for the primary tumor is not included in the provided list, specify the histological subtype.
39	Prior malignancy (of the same cancer type)	☐ Yes ☐ No ☐ Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
40	Prior malignancy (other cancer type)	☐ Yes ☐ No ☐ Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.
41	AJCC cancer staging edition	☐ 1st ☐ 2nd ☐ 3rd ☐ 4th ☐ 5th ☐ 6th ☐ 7th ☐ 8th	2722309	Select the AJCC staging handbook edition used to stage the patient's primary tumor.
42	Clinical stage group	☐ Stage 0 ☐ Stage IA ☐ Stage IA1 ☐ Stage IA2 ☐ Stage IA3 ☐ Stage IB ☐ Stage II ☐ Stage IIA ☐ Stage IIB ☐ Stage III ☐ Stage IIIA ☐ Stage IIIB ☐ Stage IIIC ☐ Stage IV ☐ Stage IVA ☐ Stage IVB	3440332	Using the patient's pathology/laboratory report, select the clinical stage group of the primary tumor as defined by the American Joint Committee on Cancer (AJCC).
43	AJCC pathologic spread: Primary tumor (pT)	☐ T0 ☐ Tis ☐ Tis (SCIS) ☐ Tis (AIS) ☐ T1mi ☐ T1a ☐ T1b ☐ T1c ☐ T2a ☐ T2b ☐ T3 ☐ T4 ☐ TX	3045435	Using the patient's pathology/laboratory report, select the code for the pathologic T (primary tumor) as defined by the American Joint Committee on Cancer (AJCC).
44	AJCC pathologic spread: Lymph nodes (pN)	☐ N0 ☐ N1 ☐ N2 ☐ N3 ☐ NX	3203106	Using the patient's pathology/laboratory report, select the code for the pathologic N (nodal) as defined by the American Joint Committee on Cancer (AJCC).
45	AJCC pathologic spread: Distant metastases (pM)	☐ M0 ☐ M1 ☐ M1a ☐ M1b ☐ M1c ☐ MX	3045439	Using the patient's pathology/laboratory report, select the code for the pathologic M (metastasis) as defined by the American Joint Committee on Cancer (AJCC).



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
46	Tumor stage (pathological)	☐ Stage 0 ☐ Stage IA ☐ Stage IA1 ☐ Stage IA2 ☐ Stage IA3 ☐ Stage IB ☐ Stage II ☐ Stage IIA ☐ Stage IIB ☐ Stage III ☐ Stage IIIA ☐ Stage IIIB ☐ Stage IIIC ☐ Stage IV ☐ Stage IVA ☐ Stage IVB	3065862	Using the patient's pathology/laboratory report, in conjunction with the patient's medical record, select the stage as defined by the American Joint Committee on Cancer (AJCC).
47	Tumor grade	☐ G1-Well differentiated ☐ G2-Moderately differentiated ☐ G3-Poorly differentiated ☐ G4-Undifferentiated ☐ GB-Borderline histologic grade ☐ GX-Unknown	2785839	Using the patient's pathology/laboratory report, select the grade of the primary tumor.
Prognostic/Predictive/Lifestyle Features for Primary Tumor Prognosis or Responsiveness to Treatment				
48	Was KRAS mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6060079	Indicate whether KRAS mutation analysis was performed. ***Note: If KRAS mutation analysis was not performed, skip to Question 51.***
49	Was a mutation in KRAS identified?	☐ Yes ☐ No	6060081	Indicate whether a mutation in KRAS was identified through mutation analysis. ***Note: If KRAS mutation was not identified, skip to Question 51.***
50	If KRAS mutation identified, which one?	☐ G12A ☐ G12C ☐ G12D ☐ G12R ☐ G12S ☐ G12V ☐ G13A ☐ G13C ☐ G13D ☐ G13R ☐ G13V ☐ Q61H ☐ Q61L ☐ A146T ☐ Other (specify)	6060083	Indicate the specific KRAS mutation identified. ***Note: If the KRAS mutation is not listed, proceed to Question 50a, otherwise, skip to Question 51.***
50a	Other KRAS mutation(s)	_____	6101691	If the KRAS mutation identified is not provided in the previous list, specify the KRAS mutation.
51	Was EGFR mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063955	Indicate whether EGFR mutation analysis was performed. ***Note: If EGFR mutation analysis was not performed, skip to Question 54.***
52	Was a mutation in EGFR identified?	☐ Yes ☐ No	6063530	Indicate whether a mutation in EGFR was identified through mutation analysis. ***Note: If EGFR mutation was not identified, skip to Question 54.***
53	If EGFR mutation identified, which one?	☐ G719X ☐ T790M ☐ C797S ☐ L858R ☐ L861Q ☐ Exon 19 deletion ☐ Exon 20 insertion ☐ Other (specify)	3147627	Indicate the specific EGFR mutation identified. ***Note: If the EGFR mutation is not listed, proceed to Question 53a, otherwise, skip to Question 54.***
53a	Other EGFR mutation(s)	_____	4173882	If the EGFR mutation identified is not provided in the previous list, specify the EGFR mutation.
54	Was BRAF mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6061813	Indicate whether BRAF mutation analysis was performed. ***Note: If BRAF mutation analysis was not performed, skip to Question 57.***
55	Was a mutation in BRAF identified?	☐ Yes ☐ No	6061809	Indicate whether a mutation in BRAF was identified through mutation analysis. ***Note: If BRAF mutation was not identified, skip to Question 57.***
56	If BRAF mutation identified, which one?	☐ V600D ☐ V600E ☐ V600K ☐ V600R ☐ K601E ☐ Other (specify)	6061810	Indicate the specific BRAF mutation identified. ***Note: If the BRAF mutation is not listed, proceed to Question 56a, otherwise, skip to Question 57.***
56a	Other BRAF mutation	_____	6101687	If the BRAF mutation identified is not provided in the previous list, specify the BRAF mutation.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
57	Was MET mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6078874	Indicate whether MET mutation analysis was performed. ***Note: If MET mutation analysis was not performed, skip to Question 60.***
58	Was a mutation in MET identified?	☐ Yes ☐ No	6078886	Indicate whether a mutation in MET was identified through mutation analysis. ***Note: If MET mutation was not identified, skip to Question 60.***
59	If MET mutation identified, which one?	☐ D963 splice mutation ☐ D1010N ☐ D1010 splice mutation ☐ Intron 13 mutation ☐ Intron 14 mutation ☐ Exon 14 mutation ☐ Exon 14 deletion ☐ Other (specify)	6078901	Indicate the specific MET mutation identified. ***Note: If the MET mutation is not listed, proceed to Question 59a, otherwise, skip to Question 60.***
59a	Other MET mutation	_____	6230525	If the BRAF mutation is not included in the list provided, specify the MET mutation identified.
60	Was EML4-ALK translocation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063976	Indicate whether EML4-ALK translocation analysis was performed. ***Note: If EML4-ALK translocation analysis was not performed, skip to Question 64.***
61	Was an EML4-ALK translocation identified?	☐ Yes ☐ No	6063959	Indicate whether an EML4-ALK translocation was identified. ***Note: If EML4-ALK translocation was not identified, skip to Question 64.***
62	If EML4-ALK translocation found, which variant?	☐ Variant 1 ☐ Variant 2 ☐ Variant 3 ☐ Variant 4 ☐ Variant 5	3139445	Indicate the EML4-ALK translocation variant that was identified.
63	What method was used to identify the EML4-ALK translocation	☐ Cytogenetics ☐ FISH ☐ NGS ☐ IHC (nuclear staining) ☐ RT-PCR ☐ Other	3139449	Specify the method used to identify the EML4-ALK translocation variant.
64	Was ROS1 FISH performed?	☐ Yes ☐ No ☐ Unknown	6078871	Indicate whether fluorescence in situ hybridization (FISH) analysis of the ROS1 gene was performed. ***Note: If ROS FISH was not performed, skip to Question 66.***
65	Was ROS1 rearrangement detected by FISH?	☐ Yes ☐ No	6078881	Indicate whether a ROS1 rearrangement was identified by fluorescence in situ hybridization (FISH).
66	Was RET gene rearrangement analysis performed?	☐ Yes ☐ No ☐ Unknown	6078872	Indicate whether RET gene rearrangement analysis was performed. ***Note: If RET rearrangement analysis was not performed, skip to Question 68.***
67	Was a RET rearrangement identified?	☐ Yes ☐ No	6078882	Indicate whether a RET rearrangement was identified.
68	Was PD-L1 IHC performed?	☐ Yes ☐ No ☐ Unknown	6078873	Indicate whether PD-L1 expression was assessed by immunohistochemistry (IHC). ***Note: If PD-L1 IHC was not performed, skip to Question 70.***
69	PD-L1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	4798631	Indicate the status of PD-L1 protein expression as determined by immunohistochemistry (IHC).
70	Was HER2 IHC performed?	☐ Yes ☐ No ☐ Unknown	6063454	Indicate whether HER2 expression was assessed by immunohistochemistry (IHC). ***Note: If HER2 IHC was not performed, skip to Question 72.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
71	HER2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	2957563	Indicate the expression of HER2 as assessed by immunohistochemistry (IHC).
Primary Tumor Sample Information				
72	Are you submitting a primary tumor tissue sample for this case?	☐ Yes ☐ No		***If yes, proceed to question 73.*** ***If submitting a metastatic/recurrent tumor sample, proceed to Question 99.***
73	Primary tumor biospecimen ordinal	_____	6584265	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number should be "1".***
74	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
75	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
76	Sample represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this primary tumor specimen represent the PRIMARY DIAGNOSIS for this Case ID3? ***Note: If no, continue to Question 77, otherwise, skip to Question 78.***
77	Specify the ICD-10 code	_____	3226287	Provide the ICD-10 code for the primary tumor used to generate the model submitted to HCMI.
78	Tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the tumor tissue sample collected for molecular characterization.
79	Anatomic Site of tumor from which Model was Derived	☐ Left lower lobe lung ☐ Left upper lobe lung ☐ Right lower lobe lung ☐ Right middle lobe lung ☐ Right upper lobe lung ☐ Adrenal gland ☐ Bone ☐ Brain ☐ Bronchus ☐ Liver ☐ Lymph node ☐ Other (specify)	4214629	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI. ***Note: If the tissue or organ of origin is not listed, proceed to Question 79a. Otherwise, skip to Question 80.***
79a	Other anatomic site from which the tumor was obtained	_____	5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.
80	Method of cancer sample procurement	☐ Cytology ☐ Fine needle aspiration biopsy ☐ Incisional biopsy ☐ Excisional biopsy ☐ Tumor resection ☐ Other (specify)	3103514	Provide the procedure performed to obtain the primary tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 80a, otherwise, skip to Question 81.***
80a	Specify the other method of tumor sample procurement	_____	2006730	Specify the procedure performed to obtain the primary tumor tissue, if not included in the previous list.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
81	Number of days from index date to date of tumor sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the tumor tissue submitted for HCMI.
82	Tumor tissue type	☐ Primary ☐ Additional Primary ☐ NOS	3288124	Provide the primary tumor tissue type for this sample.
Primary Tumor Model Information				
83	Primary model biospecimen ordinal	_____	6594596	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number is expected to be "1".***
84	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
85	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
86	Model represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this MODEL represent the PRIMARY DIAGNOSIS for this Case ID3?
87	Model's primary tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the PRIMARY TUMOR TISSUE from which this model is derived.
88	Model's primary tumor biospecimen ordinal	_____	6584265	Enter the biospecimen ordinal of the PRIMARY TUMOR TISSUE from which this model is derived.
Treatment Information				
89	History of neoadjuvant treatment	☐ No ☐ Yes; radiation prior to resection ☐ Yes; pharmaceutical treatment prior to resection ☐ Yes; both radiation and pharmaceutical treatment prior to resection ☐ Unknown	3382737	Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment. ***Note: Pharmaceutical therapy is addressed in Questions 90-96. Radiation therapy is addressed in Questions 97-98.***
90	Neoadjuvant chemotherapy type	☐ Cytotoxic chemotherapy ☐ Hormonal ☐ Immunotherapy (cellular and immune checkpoint) ☐ Targeted therapy (small molecule inhibitors and targeted antibodies) ☐ Not applicable	5832928	Select all neoadjuvant chemotherapy types that were administered to the patient. ***Note: Cytotoxic chemotherapy is addressed in Questions 90-92. Immunotherapy is addressed in Questions 93-94. Targeted therapy is addressed in Questions 95-96.***
91	Neoadjuvant chemotherapeutic regimen	☐ Albumin-bound paclitaxel ☐ Cisplatin ☐ Carboplatin ☐ Docetaxel ☐ Etoposide ☐ Gemcitabine ☐ Irinotecan ☐ Paclitaxel ☐ Pemetrexed ☐ Vinblastine ☐ Vinorelbine ☐ Other (specify) ☐ Chemotherapy not given	2853313	Select all chemotherapeutics used for neoadjuvant therapy. ***Note: If neoadjuvant chemotherapy was not given, skip to Question 93. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 91a, otherwise, skip to Question 92.***
91a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapies administered.
92	Days to neoadjuvant chemotherapy treatment from index date	_____	5102411	Provide the number of days from index date to the date of treatment with neoadjuvant chemotherapy.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
93	Immunotherapy	☐ Atezolizumab ☐ Ipilimumab ☐ Nivolumab ☐ Pembrolizumab ☐ Other (specify)	6078897	Specify the name of the immunotherapy administered. ***Note: Note: If immunotherapy was not administered, skip to Question 95. If the immunotherapy is not listed, proceed to Question 93a, otherwise, skip to Question 94.***
93a	Immunotherapy	_____	2953828	Specify the name of the immunotherapy administered.
94	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
95	Targeted Therapy	☐ Afatinib ☐ Alectinib ☐ ASP8273 ☐ Avitinib ☐ Bevacizumab ☐ Ceritinib ☐ Crizotinib ☐ Erlotinib ☐ Gefitinib ☐ Nazartinib ☐ Necitumumab ☐ Nivolumab ☐ Olmutinib ☐ Osimertinib ☐ PF-06747775 ☐ Ramucirumab ☐ Rociletinib ☐ Other (specify)	6078893	Select the targeted therapy administered to the patient. ***Note: If the targeted therapy regimen is not listed, proceed to Question 95a, otherwise, skip to Question 96.***
95a	Specify targeted therapy	_____	4308476	Provide the name of the targeted therapy administered to the patient.
96	Days to targeted therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with targeted therapy.
97	Radiation therapy administered type	☐ 2D conventional ☐ 3D conformal ☐ Brachytherapy HDR ☐ Brachytherapy LDR ☐ IMRT ☐ Proton Beam ☐ Stereotactic Body RT ☐ Stereotactic Radiosurgery ☐ WBRT ☐ Other (specify) ☐ Unspecified ☐ Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. ***Note: If radiation therapy was not administered, proceed to Question 99. If the radiation therapy is not listed, proceed to Question 97a, otherwise, skip to Question 98.***
97a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
98	Days to radiation treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with radiation therapy.
Metastatic/Recurrent Tumor Biospecimen Information				
99	Are you submitting a metastatic/ recurrent tumor tissue sample?	☐ Yes ☐ No		Indicate whether a metastatic/recurrent tumor biospecimen was collected for this ID3 case. ***Note: If yes, proceed to Question 100. If submitting an OTHER tissue sample, proceed to Question 191.***
100	Metastatic/ recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1", the second should be number "2", etc.***
101	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
102	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
103	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
104	Number of days from index date to date of diagnosis of metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic/recurrent disease.
105	Method of metastatic/ recurrent cancer sample procurement	☐ Cytology ☐ Fine needle aspiration biopsy ☐ Incisional biopsy ☐ Excisional biopsy ☐ Tumor resection ☐ Other (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 105a, otherwise, skip to Question 106.***
105a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
106	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
107	Metastatic/ recurrent site	☐ Left lower lobe lung ☐ Left upper lobe lung ☐ Right lower lobe lung ☐ Right middle lobe lung ☐ Right upper lobe lung ☐ Adrenal gland ☐ Bone ☐ Brain ☐ Liver ☐ Lung ☐ Lymph node(s)-non-regional ☐ Other (specify)	6587394	Select the site from which the metastatic/ recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 107a, otherwise, skip to Question 108.***
107a	Other metastatic/ recurrent site	_____	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
108	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
109	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
110	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
111	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
112	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
113	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
114	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
115	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
Prognostic/Predictive/Lifestyle Features for Metastatic/Recurrent Tumor Prognosis or Responsiveness to Treatment				
116	Was KRAS mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6060079	Indicate whether KRAS mutation analysis was performed. ***Note: If KRAS mutation analysis was not performed, skip to Question 119.***
117	Was a mutation in KRAS identified?	☐ Yes ☐ No	6060081	Indicate whether a mutation in KRAS was identified through mutation analysis. ***Note: If KRAS mutation was not identified, skip to Question 119.***
118	If KRAS mutation identified, which one?	☐ G12A ☐ G12C ☐ G12D ☐ G12R ☐ G12S ☐ G12V ☐ G13A ☐ G13C ☐ G13D ☐ G13R ☐ G13V ☐ Q61H ☐ Q61L ☐ A146T ☐ Other (specify)	6060083	Indicate the specific KRAS mutation identified. ***Note: If the KRAS mutation is not listed, proceed to Question 118a, otherwise, skip to Question 119.***
118a	Other KRAS mutation(s)	_____	6101691	If the KRAS mutation identified is not provided in the previous list, specify the KRAS mutation.
119	Was EGFR mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063955	Indicate whether EGFR mutation analysis was performed. ***Note: If EGFR mutation analysis was not performed, skip to Question 122.***
120	Was a mutation in EGFR identified?	☐ Yes ☐ No	6063530	Indicate whether a mutation in EGFR was identified through mutation analysis. ***Note: If EGFR mutation was not identified, skip to Question 122.***
121	If EGFR mutation identified, which one?	☐ G719X ☐ T790M ☐ C797S ☐ L858R ☐ L861Q ☐ Exon 19 deletion ☐ Exon 20 insertion ☐ Other (specify)	3147627	Indicate the specific EGFR mutation identified. ***Note: If the EGFR mutation is not listed, proceed to Question 121a, otherwise, skip to Question 122.***
121a	Other EGFR mutation(s)	_____	4173882	If the EGFR mutation identified is not provided in the previous list, specify the EGFR mutation.
122	Was BRAF mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6061813	Indicate whether BRAF mutation analysis was performed. ***Note: If BRAF mutation analysis was not performed, skip to Question 125.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
123	Was a mutation in BRAF identified?	☐ Yes ☐ No	6061809	Indicate whether a mutation in BRAF was identified through mutation analysis. ***Note: If BRAF mutation was not identified, skip to Question 125.***
124	If BRAF mutation identified, which one?	☐ V600D ☐ V600E ☐ V600K ☐ V600R ☐ K601E ☐ Other (specify)	6061810	Indicate the specific BRAF mutation identified. ***Note: If the BRAF mutation is not listed, proceed to Question 124a, otherwise, skip to Question 125.***
124a	Other BRAF mutation	☐ _____	6101687	If the BRAF mutation identified is not provided in the previous list, specify the BRAF mutation.
125	Was MET mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6078874	Indicate whether MET mutation analysis was performed. ***Note: If MET mutation analysis was not performed, skip to Question 128.***
126	Was a mutation in MET identified?	☐ Yes ☐ No	6078886	Indicate whether a mutation in MET was identified through mutation analysis. ***Note: If MET mutation was not identified, skip to Question 128.***
127	If MET mutation identified, which one?	☐ D963 splice mutation ☐ D1010N ☐ D1010 splice mutation ☐ Intron 13 mutation ☐ Intron 14 mutation ☐ Exon 14 mutation ☐ Exon 14 deletion ☐ Other (specify)	6078901	Indicate the specific MET mutation identified. ***Note: If the MET mutation is not listed, proceed to Question 127a, otherwise, skip to Question 128.***
127a	Other MET mutation	_____	6230525	If the MET mutation is not included in the list provided, specify the MET mutation identified.
128	Was EML4-ALK translocation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063976	Indicate whether EML4-ALK translocation analysis was performed. ***Note: If EML4-ALK translocation analysis was not performed, skip to Question 132.***
129	Was an EML4-ALK translocation identified?	☐ Yes ☐ No	6063959	Indicate whether an EML4-ALK translocation was identified. ***Note: If EML4-ALK translocation was not identified, skip to Question 132.***
130	If EML4-ALK translocation found, which variant?	☐ Variant 1 ☐ Variant 2 ☐ Variant 3 ☐ Variant 4 ☐ Variant 5	3139445	Indicate the EML4-ALK translocation variant that was identified.
131	What method was used to identify the EML4-ALK translocation	☐ Cytogenetics ☐ FISH ☐ NGS ☐ IHC (nuclear staining) ☐ RT-PCR ☐ Other	3139449	Specify the method used to identify the EML4-ALK translocation variant.
132	Was ROS1 FISH performed?	☐ Yes ☐ No ☐ Unknown	6078871	Indicate whether fluorescence in situ hybridization (FISH) analysis of the ROS1 gene was performed. ***Note: If ROS FISH was not performed, skip to Question 134.***
133	Was ROS1 rearrangement detected by FISH?	☐ Yes ☐ No	6078881	Indicate whether a ROS1 rearrangement was identified by fluorescence in situ hybridization (FISH).
134	Was RET gene rearrangement analysis performed?	☐ Yes ☐ No ☐ Unknown	6078872	Indicate whether RET gene rearrangement analysis was performed. ***Note: If RET rearrangement analysis was not performed, skip to Question 136.***
135	Was a RET rearrangement identified?	☐ Yes ☐ No	6078882	Indicate whether a RET rearrangement was identified.



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Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
136	Was PD-L1 IHC performed?	☐ Yes ☐ No ☐ Unknown	6078873	Indicate whether PD-L1 expression was assessed by immunohistochemistry (IHC). ***Note: If PD-L1 IHC was not performed, skip to Question 138.***
137	PD-L1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	4798631	Indicate the status of PD-L1 protein expression as determined by immunohistochemistry (IHC).
138	Was HER2 IHC performed?	☐ Yes ☐ No ☐ Unknown	6063454	Indicate whether HER2 expression was assessed by immunohistochemistry (IHC). ***Note: If HER2 IHC was not performed, skip to Question 140.***
139	HER2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	2957563	Indicate the expression of HER2 as assessed by immunohistochemistry (IHC).
Additional Metastatic/Recurrent Tumor Biospecimen Information (if applicable)				
140	Are you submitting an additional metastatic/ recurrent tumor tissue sample?	☐ Yes ☐ No		A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen. ***Note: If yes, proceed to Question 141, otherwise, skip to Question 181.***
141	Metastatic/ recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. The first biospecimen should be number "1," the second should be number "2," etc.
142	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
143	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
144	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
145	Number of days from index date to date of diagnosis of additional metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of additional metastatic/recurrent disease.
146	Method of metastatic/ recurrent cancer sample procurement	☐ Cytology ☐ Fine needle aspiration biopsy ☐ Incisional biopsy ☐ Excisional biopsy ☐ Tumor resection ☐ Other (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 146a, otherwise, skip to Question 147.***
146a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.



Enrollment: Lung

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
147	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
148	Metastatic/ recurrent site	☐ Left lower lobe lung ☐ Left upper lobe lung ☐ Right lower lobe lung ☐ Right middle lobe lung ☐ Right upper lobe lung ☐ Adrenal gland ☐ Bone ☐ Brain ☐ Liver ☐ Lung ☐ Lymph node(s)- non-regional ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 148a, otherwise, skip to Question 149.***
148a	Other metastatic/ recurrent site	_____	6587395	If not included in the previous list, specify the site from which the metastatic/ recurrent tissue used to develop the model was derived.
149	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
150	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
151	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
152	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
153	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
154	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
155	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.



Enrollment: Lung

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
156	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
Prognostic/Predictive/Lifestyle Features for Additional Metastatic/Recurrent Tumor Prognosis or Responsiveness to Treatment				
157	Was KRAS mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6060079	Indicate whether KRAS mutation analysis was performed. ***Note: If KRAS mutation analysis was not performed, skip to Question 160.***
158	Was a mutation in KRAS identified?	☐ Yes ☐ No	6060081	Indicate whether a mutation in KRAS was identified through mutation analysis. ***Note: If KRAS mutation was not identified, skip to Question 160.***
159	If KRAS mutation identified, which one?	☐ G12A ☐ G12V ☐ G13V ☐ G12C ☐ G13A ☐ Q61H ☐ G12D ☐ G13C ☐ Q61L ☐ G12R ☐ G13D ☐ A146T ☐ G12S ☐ G13R ☐ Other (specify)	6060083	Indicate the specific KRAS mutation identified. ***Note: If the KRAS mutation is not listed, proceed to Question 159a, otherwise, skip to Question 160.***
159a	Other KRAS mutation(s)	_____	6101691	If the KRAS mutation identified is not provided in the previous list, specify the KRAS mutation.
160	Was EGFR mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063955	Indicate whether EGFR mutation analysis was performed. ***Note: If EGFR mutation analysis was not performed, skip to Question 163.***
161	Was a mutation in EGFR identified?	☐ Yes ☐ No	6063530	Indicate whether a mutation in EGFR was identified through mutation analysis. ***Note: If EGFR mutation was not identified, skip to Question 163.***
162	If EGFR mutation identified, which one?	☐ G719X ☐ L861Q ☐ T790M ☐ Exon 19 deletion ☐ C797S ☐ Exon 20 insertion ☐ L858R ☐ Other (specify)	3147627	Indicate the specific EGFR mutation identified. ***Note: If the EGFR mutation is not listed, proceed to Question 162a, otherwise, skip to Question 163.***
162a	Other EGFR mutation(s)	_____	4173882	If the EGFR mutation identified is not provided in the previous list, specify the EGFR mutation.
163	Was BRAF mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6061813	Indicate whether BRAF mutation analysis was performed. ***Note: If BRAF mutation analysis was not performed, skip to Question 166.***
164	Was a mutation in BRAF identified?	☐ Yes ☐ No	6061809	Indicate whether a mutation in BRAF was identified through mutation analysis. ***Note: If BRAF mutation was not identified, skip to Question 166.***
165	If BRAF mutation identified, which one?	☐ V600D ☐ V600R ☐ V600E ☐ K601E ☐ V600K ☐ Other (specify)	6061810	Indicate the specific BRAF mutation identified. ***Note: If the BRAF mutation is not listed, proceed to Question 165a, otherwise, skip to Question 166.***
165a	Other BRAF mutation	_____	6101687	If the BRAF mutation identified is not provided in the previous list, specify the BRAF mutation.
166	Was MET mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6078874	Indicate whether MET mutation analysis was performed. ***Note: If MET mutation analysis was not performed, skip to Question 169.***
167	Was a mutation in MET identified?	☐ Yes ☐ No	6078886	Indicate whether a mutation in MET was identified through mutation analysis. ***Note: If MET mutation was not identified, skip to Question 169.***



Enrollment: Lung

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
168	If MET mutation identified, which one?	☐ D963 splice mutation ☐ D1010N ☐ D1010 splice mutation ☐ Intron 13 mutation ☐ Intron 14 mutation ☐ Exon 14 mutation ☐ Exon 14 deletion ☐ Other (specify)	6078901	Indicate the specific MET mutation identified. ***Note: If the MET mutation is not listed, proceed to Question 168a, otherwise, skip to Question 169.***
168a	Other MET mutation	_____	6230525	If the BRAF mutation is not included in the list provided, specify the MET mutation identified.
169	Was EML4-ALK translocation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063976	Indicate whether EML4-ALK translocation analysis was performed. ***Note: If EML4-ALK translocation analysis was not performed, skip to Question 173.***
170	Was an EML4-ALK translocation identified?	☐ Yes ☐ No	6063959	Indicate whether an EML4-ALK translocation was identified. ***Note: If EML4-ALK translocation was not identified, skip to Question 173.***
171	If EML4-ALK translocation found, which variant?	☐ Variant 1 ☐ Variant 2 ☐ Variant 3 ☐ Variant 4 ☐ Variant 5	3139445	Indicate the EML4-ALK translocation variant that was identified.
172	What method was used to identify the EML4-ALK translocation	☐ Cytogenetics ☐ FISH ☐ NGS ☐ IHC (nuclear staining) ☐ RT-PCR ☐ Other	3139449	Specify the method used to identify the EML4-ALK translocation variant.
173	Was ROS1 FISH performed?	☐ Yes ☐ No ☐ Unknown	6078871	Indicate whether fluorescence in situ hybridization (FISH) analysis of the ROS1 gene was performed. ***Note: If ROS FISH was not performed, skip to Question 175.***
174	Was ROS1 rearrangement detected by FISH?	☐ Yes ☐ No	6078881	Indicate whether a ROS1 rearrangement was identified by fluorescence in situ hybridization (FISH).
175	Was RET gene rearrangement analysis performed?	☐ Yes ☐ No ☐ Unknown	6078872	Indicate whether RET gene rearrangement analysis was performed. ***Note: If RET rearrangement analysis was not performed, skip to Question 177.***
176	Was a RET rearrangement identified?	☐ Yes ☐ No	6078882	Indicate whether a RET rearrangement was identified.
177	Was PD-L1 IHC performed?	☐ Yes ☐ No ☐ Unknown	6078873	Indicate whether PD-L1 expression was assessed by immunohistochemistry (IHC). ***Note: If PD-L1 IHC was not performed, skip to Question 179.***
178	PD-L1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	4798631	Indicate the status of PD-L1 protein expression as determined by immunohistochemistry (IHC).
179	Was HER2 IHC performed?	☐ Yes ☐ No ☐ Unknown	6063454	Indicate whether HER2 expression was assessed by immunohistochemistry (IHC). ***Note: If HER2 IHC was not performed, skip to Question 181.***
180	HER2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	2957563	Indicate the expression of HER2 as assessed by immunohistochemistry (IHC).



Enrollment: Lung

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Metastatic/Recurrent Tumor Model Information				
181	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
182	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
183	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
184	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
185	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Additional Metastatic/Recurrent Biospecimen Tumor Model Information (if applicable)				
186	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
187	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
188	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
189	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
190	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Other Biospecimen Information				
191	Are you submitting an OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an OTHER tissue sample (e.g. pre-malignant, non-malignant, or dysplastic tissue, etc.) was collected for HCMI for this case. ***Note: If yes, proceed to Question 192.***
192	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***



Enrollment: Lung

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
193	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
194	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
195	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
196	Other method of cancer sample procurement	☐ Cytology ☐ Fine needle aspiration biopsy ☐ Incisional biopsy ☐ Excisional biopsy ☐ Tumor resection ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 196a, otherwise, skip to Question 197.***
196a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
197	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
198	Tissue type	☐ Pre-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 198a, otherwise, skip to Question 199.***
198a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
199	Anatomic site of OTHER tissue	☐ Left lower lobe lung ☐ Left upper lobe lung ☐ Right lower lobe lung ☐ Right middle lobe lung ☐ Right upper lobe lung ☐ Adrenal gland ☐ Bone ☐ Brain ☐ Liver ☐ Lung ☐ Lymph node(s)- non-regional ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 199a, otherwise, skip to Question 200.***
199a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.
200	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
201	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Additional OTHER biospecimen Information (if applicable)				



Enrollment: Lung

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
202	Are you submitting an additional OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an additional OTHER tissue sample (pre-malignant, non-malignant, or dysplastic tissue, etc.) is being submitted for HCMI for this case. ***Note: If yes, proceed to Question 203, otherwise, skip to Question 213.***
203	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
204	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
205	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
206	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
207	Other method of cancer sample procurement	☐ Cytology ☐ Fine needle aspiration biopsy ☐ Incisional biopsy ☐ Excisional biopsy ☐ Tumor resection ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 207a, otherwise, skip to Question 208.***
207a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
208	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
209	Tissue type	☐ Pre-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 209a, otherwise, skip to Question 210.***
209a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
210	Anatomic site of OTHER tissue	☐ Left lower lobe lung ☐ Left upper lobe lung ☐ Right lower lobe lung ☐ Right middle lobe lung ☐ Right upper lobe lung ☐ Adrenal gland ☐ Bone ☐ Brain ☐ Liver ☐ Lung ☐ Lymph node(s)- non-regional ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 210a, otherwise, skip to Question 211.***



Enrollment: Lung

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
210a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.
211	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
212	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Other Tissue Model Information				
213	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
214	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
215	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
216	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
217	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.
Additional Other Tissue Model Information (if applicable)				
218	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
219	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
220	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
221	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
222	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.



Enrollment: Melanoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Form Notes: An Enrollment Form should be completed for each HCMI case upon qualification notice from Leidos. All information provided on this form should include activity from the Date of Initial Pathologic Diagnosis to the most recent Date of Last Contact with the patient.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	☐ Initial pathologic diagnosis ☐ Sample procurement ☐ First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.
Patient Information				
4	Gender	☐ Male ☐ Female ☐ Unspecified	2200604	Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
5	Height	_____	649	Provide the patient's height, in centimeters.
6	Weight	_____	651	Provide the patient's weight, in kilograms.
7	Body mass index (BMI)	_____	2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
8	Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown ☐ Not reported	2192199	Provide the patient's race using the defined categories. **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 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. **Black or African American:** A person having origins in any of the black racial groups of Africa. **Native Hawaiian or other Pacific Islander:** A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island. **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
9	Ethnicity	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Not reported	2192217	Provide the patient's ethnicity using the defined categories. **Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. **Not Hispanic or Latino:** A person not meeting the definition of Hispanic or Latino.
10	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.



Enrollment: Melanoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
11	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. ***Note: If the patient's age is greater than 32,872 days (90 years), please enter 32,872.***
12	Year of birth	_____	2896954	Provide the year of the patient's birth. If the patient was born prior to 1928, insert the date 1928.
13	Family history of cancer	☐ Same ☐ Different ☐ None ☐ Unknown	5832923	Has a first-degree relative of the patient been diagnosed with a cancer of the same or a different type?
14	Smoking history	☐ Lifelong non-smoker (<100 cigarettes smoked in a lifetime) ☐ Current smoker (includes daily and non-daily smokers) ☐ Current reformed smoker (duration not specified) ☐ Current reformed smoker for >15 years ☐ Current reformed smoker for ≤15 years	2181650	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories.
15	Metastasis at diagnosis assessment status	☐ Metastatic ☐ Non-metastatic (confirmed) ☐ Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor. ***Note: If metastatic at diagnosis, proceed to Question 16, otherwise, skip to Question 17.***
16	Metastatic site(s) at diagnosis	☐ Brain ☐ Lung ☐ Skin/subcutaneous ☐ Other (specify)	3029815	Indicate the site(s) of metastasis at the time of diagnosis of the primary tumor. ***Note: If the anatomic site of tumor tissue is not listed, proceed to Question 16a, otherwise, skip to Question 17.***
16b	Specify metastatic site(s)	_____	3128033	If the site of metastasis is not included on the provided list, specify the site of metastasis.
Biospecimen Information				
17	Tissue sample type(s) collected for HCMI for this case	☐ Normal tissue ☐ Primary tumor ☐ Metastatic ☐ Recurrent ☐ Other tissue	2006911	Please select all the tissue sample types submitted for HCMI with this case.
18	Number of NORMAL tissues biospecimens collected for HCMI for this case	_____	6584256	Please provide the number of normal tissue specimens obtained for HCMI for this case. ***Note: This number is expected to be 1.***
19	Number of PRIMARY cancer tissue biospecimens collected for HCMI model development for this case	_____	6584257	Please provide the number of primary tumor specimens obtained for HCMI for this case. ***Note: A single primary tumor biospecimen obtained that is portioned for both sequencing and model generation counts as 1 single primary tumor specimen. This number is expected to be 1.***
20	Number of METASTATIC/RECURRENT cancer tissue biospecimens collected for HCMI model development for this case	_____	6584258	Please provide the number of metastatic and/or recurrent cancer biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***



Enrollment: Melanoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
21	Number of OTHER tissue biospecimens collected for HCMI model development for this case	_____	6584259	Please provide the number of pre-malignant, non-malignant, or dysplastic tissue biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
22	Total number of tissue biospecimens collected for HCMI for this case	_____	6584271	Please provide the total number of tissue biospecimens collected for HCMI for this case. ***Note: This number should be the sum of the normal, primary tumor, metastatic/recurrent tumor, and other biospecimen counts above.***
Normal Control Information				
23	Normal tissue biospecimen ordinal	_____	6584264	Please provide a number to identify which biospecimen this is in the sequence. ***The first biospecimen should be number "1," the second should be number "2," etc.***
24	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
25	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
26	Type of normal control	☐ Whole blood ☐ Buccal cells ☐ Buffy coat ☐ Lymphocytes ☐ Extracted DNA from blood ☐ Extracted DNA from saliva ☐ Extracted DNA from buccal cells ☐ Extracted DNA from normal tissue ☐ FFPE non-neoplastic tissue ☐ Non-neoplastic tissue	3081936	Indicate the type of normal control submitted for this case.
27	Anatomic site of normal tissue	☐ Skin ☐ Fibroadipose tissue ☐ Other (specify)	4132152	If non-neoplastic tissue was submitted as the normal control, select the anatomic site of the normal tissue. ***Note: If the anatomic site of normal tissue is not listed, proceed to Question 27a, otherwise, skip to Question 28.***
27a	Other anatomic site of normal tissue	_____	3288189	If non-neoplastic tissue, adjacent tissue, or normal tissue from another anatomic site was submitted as the normal control, provide the anatomic site of the normal tissue.
28	Distance from tumor to normal control tissue (if not blood)	☐ Adjacent (< or = 2cm) ☐ Distal (>2cm) ☐ Unknown ☐ Not applicable	3088708	Indicate the distance from the site of normal tumor collection to the primary tumor. ***Note: If normal tissue was not submitted, select 'Not applicable'.***
29	Normal tissue sample preservation method	☐ Cryopreserved ☐ OCT ☐ FFPE ☐ Snap frozen ☐ Frozen	5432521	Provide the method used to preserve the normal tissue sample collected for molecular characterization.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Primary Tumor Biospecimen Information				
30	ICD-10 code for primary tumor	☐ C43.0 ☐ C43.1 ☐ C43.2 ☐ C43.3 ☐ C43.4 ☐ C43.5 ☐ C43.6 ☐ C43.7 ☐ C43.8 ☐ C43.9 ☐ Other (specify)	3226287	Provide the ICD-10 code for the primary tumor as used to generate the ID3 for this subject. ***Note: If the ICD-10 code is not listed, proceed to Question 30a, otherwise, skip to Question 31***
30a	Other ICD-10 code for primary tumor	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.
31	Tumor Morphology	☐ 8720/3 ☐ 8721/3 ☐ 8722/3 ☐ 8723/3 ☐ 8730/3 ☐ 8740/3 ☐ 8741/3 ☐ 8742/3 ☐ 8743/3 ☐ 8745/3 ☐ 8746/3 ☐ 8761/3 ☐ 8770/3 ☐ 8771/3 ☐ 8772/3 ☐ 8773/3 ☐ 8774/3 ☐ 9044/3 ☐ Other (specify)	3226275	Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor. ***Note: If the ICD-O-3 histology code of the primary tumor is not listed, proceed to Question 31a, otherwise, skip to Question 32.***
31a	Specify other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.
32	Tissue or organ of origin	☐ Skin ☐ Other (specify)	3427536	Using the patient's pathology/laboratory report, select the primary site of the disease. ***Note: If the primary site of the disease is not listed, proceed to Question 32a, otherwise skip to Question 33.***
32a	Other tissue or organ of origin	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina	3427536	If the primary site of the disease is not included on the previous list, provide the primary site of the disease.



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		☐ Nasopharynx ☐ Vulva ☐ Nervous system ☐ Oropharynx		
Question	**Question Text**	**Data Entry Options**	**CDE ID**	**Instruction Text**
33	Histological Type	☐ Melanoma ☐ Other (specify)	3081932	Select the surgical pathology text description of the histological tumor type. ***Note: If the histological tumor type is not listed, proceed to Question 33a, otherwise, skip to Question 34.***
33a	Other histological type	_____	3294805	If the traditional surgical pathology text description of the histological tumor type is not included on the previous list, please specify the histological type.
34	Histological subtype	☐ Superficial spreading melanoma ☐ Nodular melanoma ☐ Lentigo maligna melanoma ☐ Acral lentiginous melanoma ☐ Desmoplastic melanoma ☐ Melanoma arising from blue nevus ☐ Melanoma arising in a giant congenital nevus ☐ Nevoid melanoma ☐ Melanoma, NOS ☐ Other (specify)	3081934	Using the patient's pathology/laboratory report, select the histological subtype of the primary tumor. ***Note: Only capture with distinct, pure form of melanoma at the primary site. If the histological subtype is not listed, proceed to Question 34a, otherwise, skip to Question 35.***
34a	Other histological subtype	_____	5946219	If the histological subtype for the primary tumor is not included in the provided list, specify the histological subtype.
35	Prior malignancy (of the same cancer type)	☐ Yes ☐ No ☐ Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
36	Prior malignancy (other cancer type)	☐ Yes ☐ No ☐ Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.
37	AJCC cancer staging edition	☐ 1st ☐ 4th ☐ 7th ☐ 2nd ☐ 5th ☐ 8th ☐ 3rd ☐ 6th	2722309	Select the AJCC staging handbook edition used to stage the patient's primary tumor.
38	AJCC clinical stage group	☐ Stage 0 ☐ Stage IIB ☐ Stage IA ☐ Stage IIC ☐ Stage IB ☐ Stage III ☐ Stage IIA ☐ Stage IV	3440332	Using the patient's pathology/laboratory report, select the clinical stage group of the primary tumor as defined by the American Joint Committee on Cancer (AJCC). ***Note: Should be re-staged if not using 8th edition, for consistency***
39	AJCC pathologic spread: Primary tumor (pT)	☐ TX ☐ T1b ☐ T3a ☐ T0 ☐ T2 ☐ T3b ☐ Tis ☐ T2a ☐ T4, ☐ T1 ☐ T2b ☐ T4a ☐ T1a ☐ T3 ☐ T4b	3045435	Using the patient's pathology/laboratory report, select the code for the pathologic T (primary tumor) as defined by the American Joint Committee on Cancer (AJCC). ***Note: Should be re-staged if not using 8th edition, for consistency.***
40	AJCC pathologic spread: Lymph nodes (pN)	☐ NX ☐ N1c ☐ N3 ☐ N0 ☐ N2 ☐ N3a ☐ N1 ☐ N2a ☐ N3b ☐ N1a ☐ N2b ☐ N3c ☐ N1b ☐ N2c	3203106	Using the patient's pathology/laboratory report, select the code for the pathologic N (nodal) as defined by the American Joint Committee on Cancer (AJCC). ***Note: Should be re-staged if not using 8th edition, for consistency.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
41	AJCC pathologic spread: Distant metastases (pM)	☐ M0 ☐ M1 ☐ M1a ☐ M1b ☐ M1c ☐ M1d	3045439	Using the patient's pathology/laboratory report, select the code for the pathologic M (metastasis) as defined by the American Joint Committee on Cancer (AJCC). ***Note: Should be re-staged if not using 8th edition, for consistency.***
42	AJCC tumor stage (pathological)	☐ Stage 0 ☐ Stage IA ☐ Stage IB ☐ Stage IIA ☐ Stage IIB ☐ Stage IIC ☐ Stage IIIA ☐ Stage IIIB ☐ Stage IIIC ☐ Stage IIID ☐ Stage IV	3065862	Using the patient's pathology/laboratory report, in conjunction with the patient's medical record, select the tumor stage as defined by the American Joint Committee on Cancer (AJCC). ***Note: Should be re-staged if not using 8th edition, for consistency.***
43	Lymphovascular invasion present?	☐ Yes ☐ No ☐ Unknown	64727	Indicate whether large vessel (vascular) invasion or small, thin-walled (lymphatic) invasion was detected in the primary tumor.
44	Perineural invasion present?	☐ Yes ☐ No ☐ Unknown	64181	Indicate whether perineural invasion or infiltration of tumor or cancer is present.
45	Satellite nodule(s) or microsatellite(s)	☐ Present ☐ Absent ☐ Indeterminate	2431582	Indicate whether additional separate neoplastic nodules are present.
46	Number of positive lymph nodes	_____	89	Provide the number of lymph nodes with disease involvement.
47	Number of lymph nodes tested	_____	3	Provide the total number of lymph nodes tested for the presence of cancer cells.
48	Breslow thickness (mm)	_____	64809	Provide the thickness of the melanoma, also known as Breslow Thickness, in mm rounded to the nearest tenth.
Primary Tumor Clinical Molecular Characterization				
49	Was BRAF mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6061813	Indicate whether an analysis for mutation in the BRAF gene was performed.
50	Was a mutation in BRAF identified?	☐ Yes ☐ No	6061809	Indicate whether a mutation in BRAF was identified through mutation analysis.
51	If BRAF mutation identified, which one?	☐ V600E ☐ V600D ☐ V600K ☐ V600R ☐ K601E ☐ Other (specify)	6061810	Indicate the specific BRAF mutation identified. ***Note: If the BRAF mutation is not listed, proceed to Question 51a, otherwise, skip to Question 52.***
51a	Other BRAF mutation	_____	6101687	If the BRAF mutation is not included in the list provided, specify the BRAF mutation identified.
52	Was BRAF V600E IHC performed?	☐ Yes ☐ No ☐ Unknown	6428123	Indicate whether immunohistochemical analysis for the BRAF V600E mutation was performed.
53	BRAF V600E expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6428124	Indicate the expression of BRAF V600E by immunohistochemistry (IHC).
54	Was TP53 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063448	Indicate whether an analysis for mutation in the TP53 gene was performed.
55	Was a mutation in TP53 identified?	☐ Yes ☐ No	6063523	Indicate whether a mutation in TP53 was identified through mutation analysis.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
56	If TP53 mutation identified, which one?	☐ R175H ☐ R248Q ☐ R273H ☐ R213L ☐ R248W ☐ R273L ☐ Y220C ☐ G266E ☐ R282G ☐ C238Y ☐ G266V ☐ R282W ☐ G245D ☐ V272M ☐ Other (specify) ☐ G245S ☐ R273C	6063731	Indicate the specific TP53 mutation identified. ***Note: If the TP53 mutation is not listed, proceed to Question 56a, otherwise, skip to Question 57.***
56a	Other TP53 mutation(s)	_____	6101683	If the TP53 mutation identified is not provided in the previous list, specify the TP53 mutation.
57	Was NRAS mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6428125	Indicate whether an analysis for mutation in the NRAS gene was performed.
58	Was a mutation in NRAS identified?	☐ Yes ☐ No	6428126	Indicate whether a mutation in NRAS was identified through mutation analysis.
59	If NRAS mutation identified, which one?	☐ G12C ☐ G13V ☐ Q61L ☐ G12D ☐ Q61E ☐ Q61P ☐ G12S ☐ Q61H ☐ Q61R ☐ G13R ☐ Q61K ☐ Other (specify)	6430530	Indicate the specific NRAS mutation identified.
59a	Other NRAS mutation(s)	_____	6429934	If the NRAS mutation identified is not provided in the previous list, specify the NRAS mutation.
60	Was C-KIT mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6429324	Indicate whether an analysis for mutation in the C-KIT gene was performed.
61	Was a mutation in C-KIT identified?	☐ Yes ☐ No	6429327	Indicate whether a mutation in C-KIT was identified through mutation analysis.
62	If C-KIT mutation identified, which one?	☐ K642E ☐ D820Y ☐ Y846C ☐ L647F ☐ N822K ☐ S850G ☐ G648D ☐ N822Y ☐ V852I ☐ I653T ☐ A829P ☐ L859P ☐ V654A ☐ L831P ☐ L862P ☐ L813P ☐ S840I ☐ Other (specify) ☐ K818Q	6430531	Indicate the specific C-KIT mutation identified.
62a	Other C-KIT mutation(s)	_____	6429935	If the C-KIT mutation identified is not provided in the previous list, specify the C-KIT mutation.
Primary Tumor Sample Information				
63	Are you submitting a primary tumor tissue sample for this case?	☐ Yes ☐ No		***If yes, proceed to question 64.*** ***If no and submitting a metastatic/recurrent tumor sample, proceed to Question 90.***
64	Primary tumor biospecimen ordinal	_____	6584265	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number should be "1".***
65	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
66	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
67	Sample represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this primary tumor specimen represent the PRIMARY DIAGNOSIS for this Case ID3? ***Note: If no, continue to Question 68. If yes, skip to Question 69.***
68	Specify the ICD-10 code	_____	3226287	Provide the ICD-10 code for the primary tumor used to generate the model submitted to HCMI.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
69	Tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the tumor tissue sample collected for molecular characterization.
70	Anatomic Site of tumor from which Model was Derived	☐ Skin (specify) ☐ Lymph node(s) (specify) ☐ Soft tissue (specify) ☐ Bone ☐ Lung ☐ Liver ☐ Bowel ☐ Other organs (specify)	4214629	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI. ***Note: If 'Skin' is selected, proceed to Question 70a. If 'Lymph node(s)' is selected, proceed to Question 70b. If 'Soft tissue' is selected, proceed to Question 70c. If the tissue or organ of origin is not listed, proceed to Question 70d. Otherwise, skip to Question 71.***
70a	Specify the skin site from which the tumor was obtained	_____	6428112	Provide the location of the skin from which the tumor tissue sample used to generate the model for HCMI was obtained.
70b	Specify the lymph node site from which the tumor was obtained	_____	61335	Provide the location of the lymph node from which the tumor tissue sample used to generate the model for HCMI was obtained.
70c	Specify the soft tissue site from which the tumor was obtained	_____	4788416	Provide the location of the soft tissue from which the tumor tissue sample used to generate the model for HCMI was obtained.
70d	Other anatomic site from which the tumor was obtained	_____	5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.
71	Method of cancer sample procurement	☐ Excision ☐ Lymphadenectomy, regional nodes ☐ Punch biopsy ☐ Incisional biopsy ☐ Metastasectomy ☐ Other Method (specify)	3103514	Provide the procedure performed to obtain the primary tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 71a, otherwise, skip to Question 72.***
71a	Specify the other method of tumor sample procurement	_____	2006730	Specify the procedure performed to obtain the primary tumor tissue, if not included in the previous list.
72	Number of days from index date to date of tumor sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the tumor tissue submitted for HCMI.
73	Tumor tissue type	☐ Primary ☐ Additional Primary ☐ NOS	3288124	Provide the primary tumor tissue type for this sample.
Primary Tumor Model Information				
74	Primary model biospecimen ordinal	_____	6594596	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number is expected to be "1".***
75	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
76	BPC submitter ID (if available)		6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
77	Model represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this MODEL represent the PRIMARY DIAGNOSIS for this Case ID3?



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
78	Model's primary tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the PRIMARY TUMOR TISSUE from which this model is derived.
79	Model's primary tumor biospecimen ordinal	_____	6584265	Enter the biospecimen ordinal of the PRIMARY TUMOR TISSUE from which this model is derived.
Treatment Information				
80	History of neoadjuvant treatment	☐ No ☐ Yes; radiation prior to resection ☐ Yes; pharmaceutical treatment prior to resection ☐ Yes; both radiation and pharmaceutical treatment prior to resection ☐ Unknown	3382737	Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment. ***Note: Radiation therapy is addressed in Questions 88-89. Pharmaceutical therapy is addressed in Questions 81-87.***
81	Neoadjuvant chemotherapy type	☐ Cytotoxic chemotherapy ☐ Immunotherapy (cellular and immune checkpoint) ☐ Targeted therapy (small molecule inhibitors and targeted antibodies) ☐ Not applicable	5832928	Select all neoadjuvant chemotherapy types that were administered to the patient. ***Note: Cytotoxic chemotherapy is addressed in Questions 81-83. Immunotherapy is addressed in Questions 84-85 Targeted therapy is addressed in Questions 86-87.***
82	Neoadjuvant chemotherapeutic regimen	☐ Nivolumab ☐ Pembrolizumab ☐ Vemurafenib and Cobimetinib ☐ Dabrafenib and Trametinib ☐ Encorafenib and Binimetinib ☐ Other (specify) ☐ Chemotherapy not given	2853313	Select all chemotherapeutics used for neoadjuvant therapy. ***Note: If neoadjuvant chemotherapy was not given, skip to Question 84. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 82a, otherwise, skip to Question 83.***
82a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapies administered.
83	Days to neoadjuvant chemotherapy treatment from index date	_____	5102411	Provide the number of days from index date to the date of treatment with neoadjuvant chemotherapy.
84	Immunotherapy	☐ Bacille Calmette-Guerin vaccine ☐ Imiquimod ☐ Interferon-alpha ☐ Interleukin-2 ☐ Ipilimumab ☐ Nivolumab ☐ Pembrolizumab ☐ Talimogene laherparepvec ☐ Other (specify)	6428120	Select the immunotherapy administered to the patient. ***Note: If immunotherapy was not given, proceed to Question 86. If the immunotherapy is not listed, proceed to Question 84a, otherwise, skip to Question 85.***
84a	Specify immunotherapy	_____	2953828	Provide the name of the immunotherapy administered to the patient.
85	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
86	Targeted Therapy	☐ Cobimetinib ☐ Dabrafenib ☐ Imatinib ☐ Nilotinib ☐ Trametinib ☐ Vemurafenib ☐ Other (specify)	6428117	Select the targeted molecular therapy administered to the patient. ***Note: If targeted therapy was not given, proceed to Question 88. If the targeted therapy is not listed, proceed to Question 86a, otherwise, skip to Question 87.***
86a	Specify targeted therapy	_____	4308476	Provide the name of the targeted therapy administered to the patient.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
87	Days to targeted therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with targeted therapy.
88	Radiation therapy administered type	☐ 2D conventional ☐ 3D conformal ☐ Brachytherapy HDR ☐ Brachytherapy LDR ☐ IMRT ☐ Proton Beam ☐ Stereotactic Body RT ☐ Stereotactic Radiosurgery ☐ WBRT ☐ Other (specify) ☐ Unspecified ☐ Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. ***Note: If radiation therapy was not administered, proceed to Question 90. If the radiation therapy is not listed, proceed to Question 88a, otherwise, skip to Question 89.***
88a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
89	Days to radiation treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with radiation therapy.
Metastatic/Recurrent Tumor Biospecimen Information				
90	Are you submitting a metastatic/recurrent tumor tissue sample?	☐ Yes ☐ No		Indicate whether a metastatic/recurrent tumor biospecimen was collected for this ID3 case. ***Note: If yes, proceed to Question 91. If submitting an OTHER tissue sample, proceed to Question 162.***
91	Metastatic tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1", the second should be number "2", etc.***
92	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
93	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
94	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
95	Number of days from index date to date of diagnosis of metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic/recurrent disease.
96	Method of metastatic/ recurrent cancer sample procurement	☐ Excision ☐ Lymphadenectomy, regional nodes ☐ Punch biopsy ☐ Incisional biopsy ☐ Metastasectomy ☐ Other Method (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 96a, otherwise, skip to Question 97.***
96a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
97	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
98	Metastatic/ recurrent site	☐ Brain ☐ Lung ☐ Skin/subcutaneous ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 98a, otherwise, skip to Question 99.***
98a	Other metastatic/ recurrent site	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
99	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
100	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
101	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
102	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
103	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
104	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
105	Is the patient still receiving treatment?	_____	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
106	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
Metastatic Tumor Sample: Clinical Molecular Analyses				
107	Was BRAF mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6061813	Indicate whether an analysis for mutation in the BRAF gene was performed.
108	Was a mutation in BRAF identified?	☐ Yes ☐ No	6061809	Indicate whether a mutation in BRAF was identified through mutation analysis.
109	If BRAF mutation identified, which one?	☐ V600E ☐ V600R ☐ V600D ☐ K601E ☐ V600K ☐ Other (specify)	6061810	Indicate the specific BRAF mutation identified. ***Note: If the BRAF mutation is not listed, proceed to Question 109a, otherwise, skip to Question 110.***
109a	Other BRAF mutation	_____	6101687	If the BRAF mutation is not included in the list provided, specify the BRAF mutation identified.
110	Was BRAF V600E IHC performed?	☐ Yes ☐ No ☐ Unknown	6428123	Indicate whether immunohistochemical analysis for the BRAF V600E mutation was performed.
111	BRAF V600E expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6428124	Indicate the expression of BRAF V600E by immunohistochemistry (IHC).
112	Was TP53 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063448	Indicate whether an analysis for mutation in the TP53 gene was performed.
113	Was a mutation in TP53 identified?	☐ Yes ☐ No	6063523	Indicate whether a mutation in TP53 was identified through mutation analysis.
114	If TP53 mutation identified, which one?	☐ R175H ☐ R248Q ☐ R273H ☐ R213L ☐ R248W ☐ R273L ☐ Y220C ☐ G266E ☐ R282G ☐ C238Y ☐ G266V ☐ R282W ☐ G245D ☐ V272M ☐ Other (specify) ☐ G245S ☐ R273C	6063731	Indicate the specific TP53 mutation identified. ***Note: If the TP53 mutation is not listed, proceed to Question 114a, otherwise, skip to Question 115.***
114a	Other TP53 mutation(s)	_____	6101683	If the TP53 mutation identified is not provided in the previous list, specify the TP53 mutation.
115	Was NRAS mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6428125	Indicate whether an analysis for mutation in the NRAS gene was performed.
116	Was a mutation in NRAS identified?	☐ Yes ☐ No	6428126	Indicate whether a mutation in NRAS was identified through mutation analysis.



Enrollment: Melanoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
117	If NRAS mutation identified, which one?	☐ G12C ☐ G13V ☐ Q61L ☐ G12D ☐ Q61E ☐ Q61P ☐ G12S ☐ Q61H ☐ Q61R ☐ G13R ☐ Q61K ☐ Other (specify)	6430530	Indicate the specific NRAS mutation identified. ***Note: If the NRAS mutation is not listed, proceed to Question 117a, otherwise, skip to Question 118.***
117a	Other NRAS mutation(s)	_____	6429934	If the NRAS mutation identified is not provided in the previous list, specify the NRAS mutation.
118	Was C-KIT mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6429324	Indicate whether an analysis for mutation in the C-KIT gene was performed.
119	Was a mutation in C-KIT identified?	☐ Yes ☐ No	6429327	Indicate whether a mutation in C-KIT was identified through mutation analysis.
120	If C-KIT mutation identified, which one?	☐ K642E ☐ D820Y ☐ Y846C ☐ L647F ☐ N822K ☐ S850G ☐ G648D ☐ N822Y ☐ V852I ☐ I653T ☐ A829P ☐ L859P ☐ V654A ☐ L831P ☐ L862P ☐ L813P ☐ S840I ☐ Other (specify) ☐ K818Q	6430531	Indicate the specific C-KIT mutation identified. ***Note: If the C-KIT mutation is not listed, proceed to Question 120a, otherwise, skip to Question 121.***
120a	Other C-KIT mutation(s)	_____	6429935	If the C-KIT mutation identified is not provided in the previous list, specify the C-KIT mutation.
Additional Metastatic/Recurrent Tumor Biospecimen Information (if applicable)				
121	Are you submitting an additional metastatic/ recurrent tumor tissue sample?	☐ Yes ☐ No		A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen. ***Note: If yes, proceed to Question 122. If no, proceed to Question 152.***
122	Metastatic tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. The first biospecimen should be number "1," the second should be number "2," etc.
123	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
124	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
125	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ OCT ☐ FFPE ☐ Snap frozen ☐ Frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
126	Number of days from index date to date of diagnosis of metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic/recurrent disease.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
127	Method of metastatic/ recurrent cancer sample procurement	☐ Excision ☐ Lymphadenectomy, regional nodes ☐ Punch biopsy ☐ Incisional biopsy ☐ Metastasectomy ☐ Other Method (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 127a, otherwise, skip to Question 128.***
127a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
128	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
129	Metastatic/ recurrent site	☐ Brain ☐ Lung ☐ Skin/subcutaneous ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 129a, otherwise, skip to Question 130.***
129a	Other metastatic/ recurrent site	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
130	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
131	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
132	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
133	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
134	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
135	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
136	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
137	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy. ***Note: Proceed to Question 138.***
Additional Metastatic Tumor Sample: Clinical Molecular Analyses				
138	Was BRAF mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6061813	Indicate whether an analysis for mutation in the BRAF gene was performed.
139	Was a mutation in BRAF identified?	☐ Yes ☐ No	6061809	Indicate whether a mutation in BRAF was identified through mutation analysis.
140	If BRAF mutation identified, which one?	☐ V600E ☐ V600R ☐ V600D ☐ K601E ☐ V600K ☐ Other (specify)	6061810	Indicate the specific BRAF mutation identified. ***Note: If the BRAF mutation is not listed, proceed to Question 140a, otherwise, skip to Question 141.***
140a	Other BRAF mutation	_____	6101687	If the BRAF mutation is not included in the list provided, specify the BRAF mutation identified.
141	Was BRAF V600E IHC performed?	☐ Yes ☐ No ☐ Unknown	6428123	Indicate whether immunohistochemical analysis for the BRAF V600E mutation was performed.
142	BRAF V600E expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6428124	Indicate the expression of BRAF V600E by immunohistochemistry (IHC).
143	Was TP53 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063448	Indicate whether an analysis for mutation in the TP53 gene was performed.
144	Was a mutation in TP53 identified?	☐ Yes ☐ No	6063523	Indicate whether a mutation in TP53 was identified through mutation analysis.
145	If TP53 mutation identified, which one?	☐ R175H ☐ R248Q ☐ R273H ☐ R213L ☐ R248W ☐ R273L ☐ Y220C ☐ G266E ☐ R282G ☐ C238Y ☐ G266V ☐ R282W ☐ G245D ☐ V272M ☐ Other ☐ G245S ☐ R273C (specify)	6063731	Indicate the specific TP53 mutation identified. ***Note: If the TP53 mutation is not listed, proceed to Question 145a, otherwise, skip to Question 146.***



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
145a	Other TP53 mutation(s)	_____	6101683	If the TP53 mutation identified is not provided in the previous list, specify the TP53 mutation.
146	Was NRAS mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6428125	Indicate whether an analysis for mutation in the NRAS gene was performed.
147	Was a mutation in NRAS identified?	☐ Yes ☐ No	6428126	Indicate whether a mutation in NRAS was identified through mutation analysis.
148	If NRAS mutation identified, which one?	☐ G12C ☐ G13V ☐ Q61L ☐ G12D ☐ Q61E ☐ Q61P ☐ G12S ☐ Q61H ☐ Q61R ☐ G13R ☐ Q61K ☐ Other (specify)	6430530	Indicate the specific NRAS mutation identified. ***Note: If the NRAS mutation is not listed, proceed to Question 148a, otherwise, skip to Question 149.***
148a	Other NRAS mutation(s)	_____	6429934	If the NRAS mutation identified is not provided in the previous list, specify the NRAS mutation.
149	Was C-KIT mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6429324	Indicate whether an analysis for mutation in the C-KIT gene was performed.
150	Was a mutation in C-KIT identified?	☐ Yes ☐ No	6429327	Indicate whether a mutation in C-KIT was identified through mutation analysis.
151	If C-KIT mutation identified, which one?	☐ K642E ☐ D820Y ☐ Y846C ☐ L647F ☐ N822K ☐ S850G ☐ G648D ☐ N822Y ☐ V852I ☐ I653T ☐ A829P ☐ L859P ☐ V654A ☐ L831P ☐ L862P ☐ L813P ☐ S840I ☐ Other (specify) ☐ K818Q	6430531	Indicate the specific C-KIT mutation identified. ***Note: If the C-KIT mutation is not listed, proceed to Question 151a, otherwise, skip to Question 157.***
151a	Other C-KIT mutation(s)	_____	6429935	If the C-KIT mutation identified is not provided in the previous list, specify the C-KIT mutation.
Metastatic/Recurrent Tumor Model Information				
152	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
153	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
154	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
155	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
156	Model's METASTATIC/RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Additional Metastatic/Recurrent Biospecimen Tumor Model Information (if applicable)				
157	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
158	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
159	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
160	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
161	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Other Biospecimen Information				
162	Are you submitting an OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an OTHER tissue sample (e.g. pre-malignant, non-malignant, or dysplastic tissue, etc.) was collected for HCMI for this case. ***Note: If yes, proceed to Question 163.***
163	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
164	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
165	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
166	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
167	Other method of cancer sample procurement	☐ Excision ☐ Lymphadenectomy, regional nodes ☐ Punch biopsy ☐ Incisional biopsy ☐ Metastasectomy ☐ Other Method (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 167a, otherwise, skip to Question 168.***
167a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
168	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
169	Tissue type	☐ Non-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 169a, otherwise, skip to Question 170.***
169a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
170	Anatomic site of OTHER tissue	☐ Brain ☐ Lung ☐ Skin/subcutaneous ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 170a, otherwise, skip to Question 171.***



Enrollment: Melanoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
170a	Specify anatomic site of OTHER tissue	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	6584916	Specify the site of OTHER tissue, if not in the previous list.
171	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
172	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI. ***Note: Proceed to Question 173.***
Additional OTHER biospecimen Information (if applicable)				
173	Are you submitting an additional OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an additional OTHER tissue sample (pre-malignant, non-malignant, or dysplastic tissue, etc.) is being submitted for HCMI for this case. ***Note: If yes, proceed to Question 174. If no, proceed to Question 184.***
174	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. The first biospecimen should be number "1," the second should be number "2," etc.
175	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.



Enrollment: Melanoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
176	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
177	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
178	Other method of cancer sample procurement	☐ Excision ☐ Lymphadenectomy, regional nodes ☐ Punch biopsy ☐ Incisional biopsy ☐ Metastasectomy ☐ Other Method (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 178a, otherwise, skip to Question 179.***
178a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
179	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
180	Tissue type	☐ Non-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 180a, otherwise, skip to Question 181.***
180a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
181	Anatomic site of OTHER tissue	☐ Brain ☐ Lung ☐ Skin/subcutaneous ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 181a, otherwise, skip to Question 182.***
181a	Specify anatomic site of OTHER tissue	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea	6584916	Specify the site of OTHER tissue, if not in the previous list.



Enrollment: Melanoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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		☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva		
182	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
183	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI. ***Note: Proceed to Question 189.***
Other Tissue Model Information				
184	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
185	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
186	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
187	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
188	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.
Additional Other Tissue Model Information (if applicable)				
189	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
190	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
191	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
192	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
193	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.



Enrollment: Mesothelioma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Form Notes: An Enrollment Form should be completed for each HCMI case upon qualification notice from Leidos. All information provided on this form should include activity from the Date of Initial Pathologic Diagnosis to the most recent Date of Last Contact with the patient.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	☐ Initial pathologic diagnosis ☐ Sample procurement ☐ First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.
Patient Information				
4	Gender	☐ Male ☐ Female ☐ Unspecified	2200604	Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
5	Height	_____	649	Provide the patient's height, in centimeters.
6	Weight	_____	651	Provide the patient's weight, in kilograms.
7	Body mass index (BMI)	_____	2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
8	Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown ☐ Not reported	2192199	Provide the patient's race using the defined categories. **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 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. **Black or African American:** A person having origins in any of the black racial groups of Africa. **Native Hawaiian or other Pacific Islander:** A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island. **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
9	Ethnicity	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Not reported	2192217	Provide the patient's ethnicity using the defined categories. **Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. **Not Hispanic or Latino:** A person not meeting the definition of Hispanic or Latino.



Enrollment: Mesothelioma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
10	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.
11	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. ***Note: If the patient's age is greater than 32,872 days (90 years), please enter 32,872.***
12	Year of birth	_____	2896954	Provide the year of the patient's birth. If the patient was born prior to 1928, insert the date 1928.
13	Family history of cancer	☐ Same ☐ Different ☐ None ☐ Unknown	5832923	Has a first-degree relative of the patient been diagnosed with a cancer of the same or a different type?
14	Smoking history	☐ Lifelong non-smoker (<100 cigarettes smoked in a lifetime) ☐ Current smoker (includes daily and non-daily smokers) ☐ Current reformed smoker (duration not specified) ☐ Current reformed smoker for >15 years ☐ Current reformed smoker for ≤15 years	2181650	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories.
15	Number of pack years smoked	_____	2955385	Indicate the number of pack years the patient smoked. ***Note: Numeric computed value to represent lifetime tobacco exposure defined as number of cigarettes smoked per day x number of years smoked divided by 20.***
16	Tobacco smoking quit year	_____	2228610	Provide the year the patient quit smoking tobacco.
17	Family history of mesothelioma	☐ Yes ☐ Unknown ☐ No	7614374	Indicate whether the patient has a family history of mesothelioma.
18	Asbestos exposure?	☐ Yes ☐ No ☐ Unknown	1253	Indicate whether the patient has a known past exposure to asbestos. ***Note: If asbestos exposure is yes, proceed to Question 19, otherwise, skip to Question 21.***
19	Age at first asbestos exposure	_____	3629991	Provide the age in whole years at which the patient was first exposed to asbestos.
20	Number of years of asbestos exposure	_____	3629992	Provide the length of time in whole years that the patient was exposed to asbestos.
21	Metastasis at diagnosis assessment status	☐ Metastatic ☐ Non-metastatic (confirmed) ☐ Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor. ***Note: If metastatic at diagnosis, proceed to Question 22, otherwise, skip to Question 23.***
22	Metastatic site(s) at diagnosis	☐ Contralateral pleura ☐ Lung ☐ Peritoneum ☐ Axillary lymph node(s) ☐ Cervical lymph node(s) ☐ Stomach ☐ Large intestine ☐ Small intestine ☐ Liver ☐ Kidney ☐ Adrenal gland ☐ Spleen ☐ Pericardium ☐ Other (specify)	3029815	Indicate the site(s) of metastasis at the time of diagnosis of the primary tumor. ***Note: If the anatomic site of tumor tissue is not listed, proceed to Question 22a, otherwise, skip to Question 23.***



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
22a	Specify metastatic site(s)	_____	3128033	If the site of metastasis is not included on the provided list, specify the site of metastasis.
Biospecimen Information				
23	Tissue sample type(s) collected for HCMI for this case	☐ Normal tissue ☐ Primary tumor ☐ Metastatic ☐ Recurrent ☐ Other tissue	2006911	Please select all the tissue sample types submitted for HCMI with this case.
24	Number of NORMAL tissues biospecimens collected for HCMI for this case	_____	6584256	Please provide the number of normal tissue specimens obtained for HCMI for this case. ***Note: This number is expected to be 1.***
25	Number of PRIMARY cancer tissue biospecimens collected for HCMI model development for this case	_____	6584257	Please provide the number of primary tumor specimens obtained for HCMI for this case. ***Note: A single primary tumor biospecimen obtained that is portioned for both sequencing and model generation counts as 1 single primary tumor specimen. This number is expected to be 1.***
26	Number of METASTATIC/RECURRENT cancer tissue biospecimens collected for HCMI model development for this case	_____	6584258	Please provide the number of metastatic and/or recurrent cancer biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
27	Number of OTHER tissue biospecimens collected for HCMI model development for this case	_____	6584259	Please provide the number of pre-malignant, non-malignant, or dysplastic tissue biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
28	Total number of tissue biospecimens collected for HCMI for this case	_____	6584271	Please provide the total number of tissue biospecimens collected for HCMI for this case. ***Note: This number should be the sum of the normal, primary tumor, metastatic/ recurrent tumor, and other biospecimen counts above.***
Normal Control Information				
29	Normal tissue biospecimen ordinal	_____	6584264	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
30	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
31	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
32	Type of normal control	☐ Whole blood ☐ Buccal cells ☐ Buffy coat ☐ Lymphocytes ☐ Extracted DNA from blood ☐ Extracted DNA from saliva ☐ Extracted DNA from buccal cells ☐ Extracted DNA from normal tissue ☐ FFPE non-neoplastic tissue ☐ Non-neoplastic tissue	3081936	Indicate the type of normal control submitted for this case.
33	Other anatomic site of normal tissue	_____	3288189	If non-neoplastic tissue, adjacent tissue, or normal tissue from another anatomic site was submitted as the normal control, provide the anatomic site of the normal tissue.
34	Distance from tumor to normal control tissue (if not blood)	☐ Adjacent (< or = 2cm) ☐ Distal (>2cm) ☐ Unknown ☐ Not applicable	3088708	Indicate the distance from the site of normal tumor collection to the primary tumor. ***Note: If normal tissue was not submitted, select 'Not applicable'.***
35	Normal tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the normal tissue sample collected for molecular characterization.
Primary Tumor Biospecimen Information				
36	ICD-10 code for primary tumor	☐ C45.0 ☐ C45.1 ☐ C45.2 ☐ C45.7 ☐ C45.9 ☐ Other (specify)	3226287	Provide the ICD-10 code for the primary tumor as used to generate the ID3 for this subject. ***Note: If the ICD-10 code is not listed, proceed to 36a, otherwise, skip to Question 37.***
36a	Other ICD-10 code for primary tumor	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.
37	Tumor morphology	☐ 9050/3 ☐ 9051/3 ☐ 9052/3 ☐ 9053/3 ☐ Other (specify)	3226275	Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor. ***Note: If the ICD-O-3 histology code of the primary tumor is not listed, proceed to Question 37a, otherwise, skip to Question 38.***
37a	Specify other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.
38	Tissue or organ of origin	☐ Mesothelium ☐ Other (specify)	3427536	Using the patient's pathology/laboratory report, select the primary site of the disease. ***Note: If the primary site of the disease is not listed, proceed to Question 38a, otherwise skip to Question 39.***



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
38a	Other tissue or organ of origin	_____	5946219	If the primary site of the disease is not included on the previous list, provide the primary site of the disease.
39	Anatomic site of the primary tumor	☐ Right pleura ☐ Left pleura ☐ Bilateral pleura ☐ Visceral pleura ☐ Parietal pleura ☐ Peritoneum ☐ Diaphragm ☐ Chest wall ☐ Not specified ☐ Other (specify)	6161035	Indicate the anatomic site of the primary tumor. ***Note: If the anatomic site of the primary tumor is not listed, proceed to Question 39a, otherwise skip to Question 40.***
39a	Other anatomic site	_____	6584268	If not provided in the previous list, provide the anatomic site of the primary tumor.
40	Laterality	☐ Right ☐ Left ☐ Bilateral ☐ Not specified ☐ Not a paired site	2007875	Indicate the laterality of the anatomic site of the primary tumor.
41	Histological type	☐ Mesothelioma ☐ Other (specify)	3081932	Select the surgical pathology text description of the histological tumor type. ***Note: If the histological tumor type is not listed, proceed to Question 41a, otherwise, skip to Question 42.***
41a	Other histological type	_____	3294805	If the traditional surgical pathology text description of the histological tumor type is not included on the previous list, please specify the histological type.
42	Histological subtype	☐ Epithelioid mesothelioma ☐ Sarcomatoid mesothelioma ☐ Biphasic mesothelioma ☐ Desmoplastic mesothelioma ☐ Mesothelioma (NOS) ☐ Other (specify)	3081934	Using the patient's pathology/laboratory report, select the histological subtype of the primary tumor. ***Note: If the histological subtype is not listed, proceed to Question 42a, otherwise, skip to Question 43.***
42a	Other histological subtype	_____	3124492	If the histological subtype for the primary tumor is not included in the provided list, specify the histological subtype.
43	Prior malignancy (of the same cancer type)	☐ Yes ☐ No ☐ Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
44	Prior malignancy (other cancer type)	☐ Yes ☐ No ☐ Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.
45	AJCC cancer staging edition	☐ 1st ☐ 2nd ☐ 3rd ☐ 4th ☐ 5th ☐ 6th ☐ 7th ☐ 8th	2722309	Select the AJCC staging handbook edition used to stage the patient's primary tumor.
46	AJCC clinical stage group	☐ Stage IA ☐ Stage IB ☐ Stage II ☐ Stage IIIA ☐ Stage IIIB ☐ Stage IV	3440332	Using the patient's pathology/laboratory report, select the clinical stage group of the primary tumor as defined by the American Joint Committee on Cancer (AJCC), if applicable.
47	AJCC pathologic spread: Primary tumor (pT)	☐ T0 ☐ T1 ☐ T1a ☐ T1b ☐ T2 ☐ T3 ☐ T4 ☐ TX	3045435	Using the patient's pathology/laboratory report, select the code for the pathologic T (primary tumor) as defined by the American Joint Committee on Cancer (AJCC).



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	☐ Data Entry Options	CDE ID	Instruction Text
48	AJCC pathologic spread: Lymph nodes (pN)	☐ N0 ☐ N1 ☐ N2 ☐ N3 ☐ NX	3203106	Using the patient's pathology/laboratory report, select the code for the pathologic N (nodal) as defined by the American Joint Committee on Cancer (AJCC).
49	AJCC pathologic spread: Distant metastases (pM)	☐ M0 ☐ M1 ☐ MX	3045439	Using the patient's pathology/laboratory report, select the code for the pathologic M (metastasis) as defined by the American Joint Committee on Cancer (AJCC).
50	Tumor stage (pathological)	☐ Stage IA ☐ Stage IB ☐ Stage II ☐ Stage IIIA ☐ Stage IIIB ☐ Stage IV	3065862	Using the patient's pathology/laboratory report, in conjunction with the patient's medical record, select the stage as defined by the American Joint Committee on Cancer (AJCC).
Prognostic/Predictive/Lifestyle Features for Primary Tumor Prognosis or Responsiveness to Treatment				
51	Number of positive lymph nodes	_____	89	Provide the number of lymph nodes with disease involvement.
52	Number of lymph nodes tested	_____	3	Provide the total number of lymph nodes tested for the presence of cancer cells.
53	WBC count	_____x10^3/mcL	58312	Provide the patient's absolute peripheral white blood cell count (in x10^3/mcL).
54	Platelet count	_____1000/mcL	58312	Provide the patient's absolute peripheral platelet count (in 1000/mcL).
55	Hemoglobin	_____g/dL	2190	Provide the patient's hemoglobin level (in g/dL).
56	Creatinine	_____mg/dL	2655822	Provide the amount of creatinine in the patient's blood, measured in milligrams per deciliter (mg/dL).
57	Serum mesothelin prior to treatment	_____	7604209	Provide the numerical result of serum mesothelin test prior to treatment.
58	Was other serum and/or effusion marker testing performed?	☐ Yes ☐ No ☐ Unknown	7595973	Indicate whether or not other serum and/or effusion marker testing was performed. ***Note: If other serum and/or effusion marker testing was performed, proceed to Question 59, otherwise, skip to Question 62.***
59	Identify serum and/or effusion markers tested	_____	7604488	Provide the name of the effusion and/or serum tumor marker test performed.
60	Serum and/or effusion marker value	_____	7604489	Provide the numeric result of the effusion and/or serum tumor marker test.
61	Serum and/or effusion marker units	_____	7604490	Provide the unit of measure related to the effusion and/or serum tumor marker test value.
62	Was the presence of circulating endothelial cells (CEC) examined?	☐ Yes ☐ No ☐ Unknown	7595969	Indicate whether or not the presence of circulating endothelial cells was examined. ***Note: If the presence of circulating endothelial cells was examined, proceed to Question 63, otherwise, skip to Question 65.***



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
63	Circulating endothelial cells	☐ Present ☐ Absent	7604207	Indicate whether or not circulating endothelial cells were present.
64	Number of circulating endothelial cells identified	_____	7604208	Provide the count of circulating endothelial cells in the patient's sample.
65	Blood volume (mL)	_____mL	3219439	Provide the volume of the blood sample used to count circulating endothelial cells, in mL.
66	Additional pathologic findings	☐ None identified ☐ Asbestos bodies ☐ Pleural plaque ☐ Pulmonary interstitial fibrosis ☐ Inflammation (specify) ☐ Other (specify)	7595953	Select all significant pathologic findings present in addition to the mesothelioma. ***Note: If inflammation was identified, proceed to Question 66a. If the pathologic finding is not listed, proceed to Question 66b, otherwise, skip to Question 67.***
66a	Specify inflammation type	_____	7595961	Indicate the predominant cell type or chronicity of inflammation related to mesothelioma.
66b	Specify other additional pathologic findings	_____	7595957	If not included in the previous list, indicate the additional pathologic findings related to mesothelioma.
67	Is necrosis present?	☐ Yes ☐ No ☐ Unknown	64740	Indicate whether there is evidence of localized death of cells associated with the presence of mesothelioma.
68	Treatment effect	☐ No known presurgical therapy ☐ Greater than 50% residual viable tumor ☐ Less than 50% residual viable tumor ☐ Cannot be determined	7595947	Indicate the effect of pre-surgical therapy on the mesothelioma.
69	Margins	☐ Cannot be assessed ☐ Uninvolved by mesothelioma ☐ Involved by mesothelioma, specify margin(s) ☐ Not applicable	7595944	Indicate the margin involvement by mesothelioma.
69a	Specify margins	_____	7595945	Provide the description of the margin involved by mesothelioma.
70	Residual tumor	☐ RX ☐ R0 ☐ R1 ☐ R2 ☐ Not evaluated	2608702	Indicate the status of the tissue margin following surgical resection.
71	Talc pleurodesis	☐ Yes ☐ No ☐ Unknown	7595972	Indicate whether talc pleurodesis was performed.
72	Tumor Size (for localized tumors only)	_____cm	64215	Provide the length of the largest dimension/diameter of a tumor, regardless of anatomical plane, in centimeters.
73	Tumor focality	☐ Unifocal ☐ Multifocal ☐ Unknown ☐ Cannot be determined	3174022	Indicate whether the tumor or cancer first developed in a single or multiple locations.
74	Performance status score: Eastern Cooperative Oncology Group	☐ 0: Asymptomatic ☐ 1: Symptomatic, but fully ambulatory ☐ 2: Symptomatic, in bed less than 50% of the day ☐ 3: Symptomatic, in bed more than 50% of the day, but not bed-ridden ☐ 4: Bed-ridden ☐ Not evaluated ☐ Unknown	88	Indicate the ECOG functional performance status of the patient/participant. ***Note: If performance status was determined, proceed to Question 75, otherwise, skip to Question 76.***



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
75	Number of days from index date to the date initial score obtained for the ECOG performance status scale	_____days	3479270	Provide the number of days from the index date to the date that the ECOG performance status assessment was performed.
76	Was EGP-2 IHC performed?	☐ Yes ☐ No ☐ Unknown	7595965	Indicate whether EGP-2 protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If EGP-2 IHC was not performed, skip to Question 78.***
77	EGP-2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	7601836	Indicate the status of EGP-2 protein expression as determined by immunohistochemistry (IHC).
78	Was TAG-72 IHC performed?	☐ Yes ☐ No ☐ Unknown	7595966	Indicate whether TAG-72 protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If TAG-72 IHC was not performed, skip to Question 80.***
79	TAG-72 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	7601837	Indicate the status of TAG-72 protein expression as determined by immunohistochemistry (IHC).
80	Was PD-L1 IHC performed?	☐ Yes ☐ No ☐ Unknown	6078873	Indicate whether PD-L1 protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If PD-L1 IHC was not performed, skip to Question 84.***
81	PD-L1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	4798631	Indicate the status of PD-L1 protein expression as determined by immunohistochemistry (IHC).
82	Which PD-L1 stain was used?	_____	7604210	Provide the name of the stain used to assess PD-L1 expression by IHC.
83	What is the PD-L1 percentage positive cells?	_____%	7604211	Provide the percent of cells positive for PD-L1 as assessed by IHC.
84	Was calretinin IHC performed?	☐ Yes ☐ No ☐ Unknown	7595962	Indicate whether calretinin protein expression by immunohistochemistry (IHC) analysis was performed.
85	Calretinin expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	7601833	Indicate the status of calretinin protein expression as determined by immunohistochemistry (IHC).
86	Was cytokeratin 5/6 IHC performed?	☐ Yes ☐ No ☐ Unknown	7614375	Indicate whether cytokeratin 5/6 protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If cytokeratin 5/6 IHC was not performed, skip to Question 88.***
87	Cytokeratin 5/6 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	7614376	Indicate the status of cytokeratin 5/6 protein expression as determined by immunohistochemistry (IHC).
88	Was WT-1 IHC performed?	☐ Yes ☐ No ☐ Unknown	6690712	Indicate whether WT-1 protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If WT-1 IHC was not performed, skip to Question 90.***
89	WT-1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6690723	Indicate the status of WT-1 protein expression as determined by immunohistochemistry (IHC).



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
90	Was D2-40 IHC performed?	☐ Yes ☐ No ☐ Unknown	7595963	Indicate whether D2-40 protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If D2-40 IHC was not performed, skip to Question 92.***
91	D2-40 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	7601834	Indicate the status of D2-40 protein expression as determined by immunohistochemistry (IHC).
92	Was BerEP4 IHC performed?	☐ Yes ☐ No ☐ Unknown	7595964	Indicate whether BerEP4 protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If BerEP4 IHC was not performed, skip to Question 94.***
93	BerEP4 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	7601835	Indicate the status of BerEP4 protein expression as determined by immunohistochemistry (IHC).
94	Was CEA IHC performed?	☐ Yes ☐ No ☐ Unknown	7595967	Indicate whether CEA protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If CEA IHC was not performed, skip to Question 96.***
95	CEA expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	7601838	Indicate the status of CEA protein expression as determined by immunohistochemistry (IHC).
96	Was BG8 IHC performed?	☐ Yes ☐ No ☐ Unknown	7595968	Indicate whether BG8 protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If BG8 IHC was not performed, skip to Question 98.***
97	BG8 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	7601839	Indicate the status of BG8 protein expression as determined by immunohistochemistry (IHC).
98	Was PTEN IHC performed?	☐ Yes ☐ No ☐ Unknown	6062415	Indicate whether PTEN protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If PTEN IHC was not performed, skip to Question 100.***
99	PTEN expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063672	Indicate the status of PTEN protein expression as determined by immunohistochemistry (IHC).
100	Was aquaporin-1 IHC performed?	☐ Yes ☐ No ☐ Unknown	7595970	Indicate whether aquaporin-1 protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If aquaporin-1 IHC was not performed, skip to Question 102.***
101	Aquaporin-1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	7601840	Indicate the status of aquaporin-1 protein expression as determined by immunohistochemistry (IHC).
102	Was COX-2 IHC performed?	☐ Yes ☐ No ☐ Unknown	7595971	Indicate whether COX-2 protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If COX-2 IHC was not performed, skip to Question 104.***
103	COX-2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	7601841	Indicate the status of COX-2 protein expression as determined by immunohistochemistry (IHC).



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Primary Tumor Sample Information				
104	Are you submitting a primary tumor tissue sample for this case?	☐ Yes ☐ No		***If yes, proceed to question 105. If submitting a metastatic/recurrent tumor biospecimen, proceed to Question 134.***
105	Primary tumor biospecimen ordinal	_____	6584265	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number should be "1".***
106	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
107	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
108	Sample represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this primary tumor specimen represent the PRIMARY DIAGNOSIS for this Case ID3? ***Note: If no, proceed to Question 109, otherwise, skip to Question 110.***
109	Specify the ICD-10 code	_____	3226287	Provide the ICD-10 code for the primary tumor used to generate the model submitted to HCMI.
110	Tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the tumor tissue sample collected for molecular characterization.
111	Anatomic site from which the primary tumor was obtained	☐ Right pleura ☐ Left pleura ☐ Bilateral pleura ☐ Visceral pleura ☐ Parietal pleura ☐ Peritoneum ☐ Diaphragm ☐ Chest wall ☐ Not specified ☐ Other (specify)	4214629	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI. ***Note: If the tissue or organ not listed, proceed to Question 111a. Otherwise, skip to Question 112.***
111a	Other anatomic site from which the primary tumor was obtained	_____	5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.
112	Specimen laterality	☐ Right ☐ Left ☐ Bilateral ☐ Not specified ☐ Not a paired site	2007875	Indicate the laterality of the anatomic site of the tumor tissue used to generate the model for the HCMI.
113	Method of cancer sample procurement	☐ Extrapleural pneumonectomy ☐ Extended pleurectomy/decortication ☐ Pleurectomy/decortication ☐ Partial pleurectomy ☐ Video-assisted thoracoscopic biopsy ☐ Local anaesthetic thoracoscopic biopsy ☐ CT guided biopsy ☐ Not specified ☐ Other (specify)	3103514	Provide the procedure performed to obtain the primary tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 113a, otherwise, skip to Question 114.***
113a	Specify the other method of tumor sample procurement	_____	2006730	Specify the procedure performed to obtain the primary tumor tissue, if not included in the previous list.
114	Number of days from index date to date of tumor sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the tumor tissue submitted for HCMI.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
115	Tumor tissue type	☐ Primary ☐ Additional Primary ☐ NOS	3288124	Provide the primary tumor tissue type for this sample.
Primary Tumor Model Information				
116	Primary model biospecimen ordinal	_____	6594596	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number is expected to be "1".***
117	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
118	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
119	Model represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this model represent the primary diagnosis for this Case ID3?
120	Model's primary tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the PRIMARY TUMOR TISSUE from which this model is derived.
121	Model's primary tumor biospecimen ordinal	_____	6584265	Enter the biospecimen ordinal of the PRIMARY TUMOR TISSUE from which this model is derived.
Treatment Information				
122	History of neoadjuvant treatment	☐ No ☐ Yes; radiation prior to resection ☐ Yes; pharmaceutical treatment prior to resection ☐ Yes; both radiation and pharmaceutical treatment prior to resection ☐ Unknown	3382737	Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment. ***Note: Pharmaceutical therapy is addressed in Questions 123-131. Radiation therapy is addressed in Questions 132-133.***
123	Neoadjuvant chemotherapy type	☐ Cytotoxic chemotherapy ☐ Hormonal ☐ Immunotherapy (cellular and immune checkpoint) ☐ Targeted therapy (small molecule inhibitors and targeted antibodies) ☐ Not applicable	5832928	Select all neoadjuvant chemotherapy types that were administered to the patient. ***Note: Cytotoxic chemotherapy is addressed in Questions 124-125. Hormone therapy is addressed in Questions 126-127. Immunotherapy is addressed in Questions 128-129. Targeted therapy is addressed in Questions 130-131.***
124	Neoadjuvant chemotherapeutic regimen	☐ Cisplatin and pemetrexed ☐ Gemcitabine ☐ Pemetrexed ☐ Cisplatin ☐ Carboplatin ☐ Vinorelbine ☐ Doxorubicin ☐ Navelbine ☐ Raltitrexed ☐ Other (specify)	2853313	Select all chemotherapeutics used for neoadjuvant therapy. ***Note: If neoadjuvant chemotherapy was not given, skip to Question 126. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 124a, otherwise, skip to Question 125.***
124a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapies administered.
125	Days to neoadjuvant chemotherapy treatment from index date	_____	5102411	Provide the number of days from index date to the date of treatment with neoadjuvant chemotherapy.
126	Hormone therapy	_____	2405358	Specify hormone therapy administered to patient.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
127	Days to hormone therapy treatment from index date	_____	5102411	Provide the number of days from index date to the date of treatment with hormone therapy.
128	Immunotherapy	_____	2185614	Provide the name of the immunotherapy administered to the patient.
129	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
130	Targeted therapy	_____	4308476	Provide the name of the targeted therapy administered to the patient.
131	Days to targeted therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with targeted therapy.
132	Radiation therapy administered type	☐ 2D conventional ☐ 3D conformal ☐ Brachytherapy HDR ☐ Brachytherapy LDR ☐ IMRT ☐ Proton Beam ☐ Stereotactic Body RT ☐ Stereotactic Radiosurgery ☐ WBRT ☐ Other (specify) ☐ Unspecified ☐ Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. ***Note: If radiation therapy was not administered, proceed to Question 134. If the radiation therapy is not listed, proceed to Question 132a, otherwise, skip to Question 133.***
132a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
133	Days to radiation treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with radiation therapy.
Metastatic/Recurrent Tumor Biospecimen Information				
134	Are you submitting a metastatic/recurrent tumor tissue sample?	☐ Yes ☐ No		Indicate whether a metastatic/recurrent tumor biospecimen was collected for this ID3 case. ***Note: If yes, proceed to Question 135. If submitting an OTHER tissue sample, proceed to Question 216.***
135	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1", the second should be number "2", etc.***
136	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
137	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
138	Metastatic/recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
139	Number of days from index date to date of diagnosis of metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic/recurrent disease.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
140	Method of metastatic/ recurrent cancer sample procurement	☐ Extrapleural pneumonectomy ☐ Extended pleurectomy/decortication ☐ Pleurectomy/decortication ☐ Partial pleurectomy ☐ Video-assisted thoracoscopic biopsy ☐ Local anaesthetic thoracoscopic biopsy ☐ CT guided biopsy ☐ Not specified ☐ Other Method (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 140a, otherwise, skip to Question 141.***
140a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
141	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
142	Metastatic/recurrent site	☐ Right pleura ☐ Left pleura ☐ Bilateral pleura ☐ Parietal pleura ☐ Visceral pleura ☐ Diaphragm ☐ Chest wall ☐ Contralateral pleura ☐ Lung ☐ Peritoneum ☐ Axillary lymph nodes ☐ Cervical lymph nodes ☐ Stomach ☐ Large intestine ☐ Small intestine ☐ Liver ☐ Kidney ☐ Adrenal gland ☐ Spleen ☐ Pericardium ☐ Not specified ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 142a, otherwise, skip to Question 143.***
142a	Other metastatic/ recurrent site	_____	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
143	Specimen laterality	☐ Right ☐ Left ☐ Bilateral ☐ Not specified ☐ Not a paired site	2007875	Indicate the laterality of the anatomic site of the tumor tissue used to generate the model for the HCMI.
144	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
145	ICD-10 code	☐ C45.0 ☐ C45.1 ☐ C45.2 ☐ C45.7 ☐ C45.9 ☐ C78.2 ☐ C78.0 ☐ C77.3 ☐ C77.0 ☐ C78.8 ☐ C78.4 ☐ C78.5 ☐ C78.7 ☐ C79.0 ☐ C79.7 ☐ C79.8 ☐ Other (specify)	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI. ***Note: If the ICD-10 code is not listed, proceed to Question 145a, otherwise, skip to Question 146.***
145a	Specify other ICD-10 code	_____	3226287	If not included in the previous list, provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
146	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
147	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
148	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
149	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
150	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
151	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
Prognostic/Predictive/Lifestyle Features for Metastatic/Recurrent Tumor Prognosis or Responsiveness to Treatment				
152	Number of positive lymph nodes	_____	89	Provide the number of lymph nodes with disease involvement.
153	Number of lymph nodes tested	_____	3	Provide the total number of lymph nodes tested for the presence of cancer cells.
154	Was the presence of circulating endothelial cells (CEC) examined?	☐ Yes ☐ No ☐ Unknown	7595969	Indicate whether or not the presence of circulating endothelial cells was examined. ***Note: If the presence of circulating endothelial cells was examined, proceed to Question 155, otherwise, skip to Question 158.***
155	Circulating endothelial cells	☐ Present ☐ Absent	7604207	Indicate whether or not circulating endothelial cells were present.
156	Number of circulating endothelial cells identified	_____	7604208	Provide the count of circulating endothelial cells in the patient's sample.
157	Blood volume (mL)	_____mL	3219439	Provide the volume of the blood sample used to count circulating endothelial cells, in mL.
158	Residual tumor	☐ RX ☐ R2 ☐ R0 ☐ Not evaluated ☐ R1	2608702	Indicate the status of the tissue margin following surgical resection.
159	Performance status score: Eastern Cooperative Oncology Group	☐ 0: Asymptomatic ☐ 1: Symptomatic, but fully ambulatory ☐ 2: Symptomatic, in bed less than 50% of the day ☐ 3: Symptomatic, in bed more than 50% of the day, but not bed-ridden ☐ 4: Bed-ridden ☐ Not evaluated ☐ Unknown	88	Indicate the ECOG functional performance status of the patient/participant. ***Note: If performance status was determined, proceed to Question 160, otherwise, skip to Question 161.***
160	Number of days from index date to the date initial score obtained for the ECOG performance status scale	_____days	3479270	Provide the number of days from the index date to the date that the ECOG performance status assessment was performed.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
161	Was EGP-2 IHC performed?	☐ Yes ☐ No ☐ Unknown	7595965	Indicate whether EGP-2 protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If EGP-2 IHC was not performed, skip to Question 163.***
162	EGP-2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	7601836	Indicate the status of EGP-2 protein expression as determined by immunohistochemistry (IHC).
163	Was TAG-72 IHC performed?	☐ Yes ☐ No ☐ Unknown	7595966	Indicate whether TAG-72 protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If TAG-72 IHC was not performed, skip to Question 165.***
164	TAG-72 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	7601837	Indicate the status of TAG-72 protein expression as determined by immunohistochemistry (IHC).
165	Was PD-L1 IHC performed?	☐ Yes ☐ No ☐ Unknown	6078873	Indicate whether PD-L1 protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If PD-L1 IHC was not performed, skip to Question 169.***
166	PD-L1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	4798631	Indicate the status of PD-L1 protein expression as determined by immunohistochemistry (IHC).
167	Which PD-L1 stain was used?	_____	7604210	Provide the name of the stain used to assess PD-L1 expression by IHC.
168	What is the PD-L1 percentage positive cells?	_____%	7604211	Provide the percent of cells positive for PD-L1 as assessed by IHC.
169	Was calretinin IHC performed?	☐ Yes ☐ No ☐ Unknown	7595962	Indicate whether calretinin protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If calretinin IHC was not performed, skip to Question 171.***
170	Calretinin expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	7601833	Indicate the status of calretinin protein expression as determined by immunohistochemistry (IHC).
171	Was cytokeratin 5/6 IHC performed?	☐ Yes ☐ No ☐ Unknown	7614375	Indicate whether cytokeratin 5/6 protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If cytokeratin 5/6 IHC was not performed, skip to Question 173.***
172	Cytokeratin 5/6 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	7614376	Indicate the status of cytokeratin 5/6 protein expression as determined by immunohistochemistry (IHC).
173	Was WT-1 IHC performed?	☐ Yes ☐ No ☐ Unknown	6690712	Indicate whether WT-1 protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If WT-1 IHC was not performed, skip to Question 175.***
174	WT-1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6690723	Indicate the status of WT-1 protein expression as determined by immunohistochemistry (IHC).



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
175	Was D2-40 IHC performed?	☐ Yes ☐ No ☐ Unknown	7595963	Indicate whether D2-40 protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If D2-40 IHC was not performed, skip to Question 177.***
176	D2-40 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	7601834	Indicate the status of D2-40 protein expression as determined by immunohistochemistry (IHC).
177	Was BerEP4 IHC performed?	☐ Yes ☐ No ☐ Unknown	7595964	Indicate whether BerEP4 protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If BerEP4 IHC was not performed, skip to Question 179.***
178	BerEP4 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	7601835	Indicate the status of BerEP4 protein expression as determined by immunohistochemistry (IHC).
179	Was CEA IHC performed?	☐ Yes ☐ No ☐ Unknown	7595967	Indicate whether CEA protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If CEA IHC was not performed, skip to Question 181.***
180	CEA expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	7601838	Indicate the status of CEA protein expression as determined by immunohistochemistry (IHC).
181	Was BG8 IHC performed?	☐ Yes ☐ No ☐ Unknown	7595968	Indicate whether BG8 protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If BG8 IHC was not performed, skip to Question 183.***
182	BG8 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	7601839	Indicate the status of BG8 protein expression as determined by immunohistochemistry (IHC).
183	Was PTEN IHC performed?	☐ Yes ☐ No ☐ Unknown	6062415	Indicate whether PTEN protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If PTEN IHC was not performed, skip to Question 185.***
184	PTEN expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063672	Indicate the status of PTEN protein expression as determined by immunohistochemistry (IHC).
185	Was aquaporin-1 IHC performed?	☐ Yes ☐ No ☐ Unknown	7595970	Indicate whether aquaporin-1 protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If aquaporin-1 IHC was not performed, skip to Question 187.***
186	Aquaporin-1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	7601840	Indicate the status of aquaporin-1 protein expression as determined by immunohistochemistry (IHC).
187	Was COX-2 IHC performed?	☐ Yes ☐ No ☐ Unknown	7595971	Indicate whether COX-2 protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If COX-2 IHC was not performed, skip to Question 189.***
188	COX-2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	7601841	Indicate the status of COX-2 protein expression as determined by immunohistochemistry (IHC).



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Additional Metastatic/Recurrent Tumor Biospecimen Information (if applicable)				
189	Are you submitting an additional metastatic/ recurrent tumor tissue sample?	☐ Yes ☐ No		A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen. ***Note: If yes, proceed to Question 190, otherwise, skip to Question 206.***
190	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. The first biospecimen should be number "1," the second should be number "2," etc.
191	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
192	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
193	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
194	Number of days from index date to date of diagnosis of additional metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of additional metastatic/recurrent disease.
195	Method of metastatic/ recurrent cancer sample procurement	☐ Extrapleural pneumonectomy ☐ Extended pleurectomy/decortication ☐ Pleurectomy/decortication ☐ Partial pleurectomy ☐ Video-assisted thoracoscopic biopsy ☐ Local anaesthetic thoracoscopic biopsy ☐ CT guided biopsy ☐ Not specified ☐ Other Method (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 195a, otherwise, skip to Question 196.***
195a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
196	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
197	Metastatic/ recurrent site	☐ Right pleura ☐ Left pleura ☐ Bilateral pleura ☐ Parietal pleura ☐ Visceral pleura ☐ Diaphragm ☐ Chest wall ☐ Contralateral pleura ☐ Lung ☐ Peritoneum ☐ Axillary lymph nodes ☐ Cervical lymph nodes ☐ Stomach ☐ Large intestine ☐ Small intestine ☐ Liver ☐ Kidney ☐ Adrenal gland ☐ Spleen ☐ Pericardium ☐ Not specified ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 197a, otherwise, skip to Question 198.***
197a	Other metastatic/ recurrent site	_____	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
198	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
199	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
200	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
201	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
202	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
203	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
204	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
205	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
Additional Metastatic/Recurrent Tumor Prognostic/Predictive/Lifestyle Features for Additional Metastatic/Recurrent Tumor Prognosis or Responsiveness to Treatment (Note: Questions 151-187 may be repeated to capture clinical molecular characterization information for additional metastatic/recurrent biospecimens.)				
Metastatic/Recurrent Tumor Model Information				
206	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
207	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
208	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
209	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
210	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Additional Metastatic/Recurrent Biospecimen Tumor Model Information (if applicable)				
211	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
212	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
213	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
214	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
215	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Other Biospecimen Information				
216	Are you submitting an OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an OTHER tissue sample (e.g. pre-malignant, non-malignant, or dysplastic tissue, etc.) was collected for HCMI for this case. ***Note: If yes, proceed to Question 217.***
217	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
218	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
219	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
220	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
221	Other method of cancer sample procurement	☐ Extrapleural pneumonectomy ☐ Extended pleurectomy/decortication ☐ Pleurectomy/decortication ☐ Partial pleurectomy ☐ Video-assisted thoracoscopic biopsy ☐ Local anaesthetic thoracoscopic biopsy ☐ CT guided biopsy ☐ Not specified ☐ Other Method (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 221a, otherwise, skip to Question 222.***
221a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
222	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
223	Tissue type	☐ Pre-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 223a, otherwise, skip to Question 224.***
223a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
224	Anatomic site of OTHER tissue	☐ Right pleura ☐ Left pleura ☐ Bilateral pleura ☐ Visceral pleura ☐ Parietal pleura ☐ Peritoneum ☐ Diaphragm ☐ Chest wall ☐ Not specified ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 224a, otherwise, skip to Question 225.***
224a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.
225	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
226	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Additional OTHER biospecimen Information (if applicable)				
227	Are you submitting an additional OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an additional OTHER tissue sample (pre-malignant, non-malignant, or dysplastic tissue, etc.) is being submitted for HCMI for this case. ***Note: If yes, proceed to Question 228, otherwise, skip to Question 238.***



Enrollment: Mesothelioma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
228	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
229	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
230	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
231	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
232	Other method of cancer sample procurement	☐ Extrapleural pneumonectomy ☐ Extended pleurectomy/decortication ☐ Pleurectomy/decortication ☐ Partial pleurectomy ☐ Video-assisted thoracoscopic biopsy ☐ Local anaesthetic thoracoscopic biopsy ☐ CT guided biopsy ☐ Not specified ☐ Other Method (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 232a, otherwise, skip to Question 233.***
232a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
233	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
234	Tissue type	☐ Pre-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 234a, otherwise, skip to Question 235.***
234a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
235	Anatomic site of OTHER tissue	☐ Right pleura ☐ Left pleura ☐ Bilateral pleura ☐ Visceral pleura ☐ Parietal pleura ☐ Peritoneum ☐ Diaphragm ☐ Chest wall ☐ Not specified ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 235a, otherwise, skip to Question 236.***
235a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.
236	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
237	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.



Enrollment: Mesothelioma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Other Tissue Model Information				
238	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
239	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
240	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
241	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
242	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.
Additional Other Tissue Model Information (if applicable)				
243	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
244	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
245	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
246	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
247	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.



Enrollment: Neuroblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Form Notes: An Enrollment Form should be completed for each HCMI case upon qualification notice from Leidos. All information provided on this form should include activity from the Date of Initial Pathologic Diagnosis to the most recent Date of Last Contact with the patient.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	☐ Initial pathologic diagnosis ☐ Sample procurement ☐ First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.
Patient Information				
4	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.
5	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. ***Note: If the patient's age is greater than 32,872 days (90 years), please enter 32,872.***
6	Gender	☐ Male ☐ Female ☐ Unspecified	2200604	Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
7	Height	_____	649	Provide the patient's height, in centimeters.
8	Weight	_____	651	Provide the patient's weight, in kilograms.
9	Body mass index (BMI)	_____	2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
10	Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown ☐ Not reported	2192199	Provide the patient's race using the defined categories. **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 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. **Black or African American:** A person having origins in any of the black racial groups of Africa. **Native Hawaiian or other Pacific Islander:** A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island. **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
11	Ethnicity	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Not reported	2192217	Provide the patient's ethnicity using the defined categories. **Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. **Not Hispanic or Latino:** A person not meeting the definition of Hispanic or Latino.



Enrollment: Neuroblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
12	Year of birth	_____	2896954	Provide the year of the patient's birth. If the patient was born prior to 1928, insert the date 1928.
13	Family history of cancer	☐ Same ☐ Different ☐ None ☐ Unknown	5832923	Has a first-degree relative of the patient been diagnosed with a cancer of the same or a different type?
14	Smoking history	☐ Lifelong non-smoker (<100 cigarettes smoked in a lifetime) ☐ Current smoker (includes daily and non-daily smokers) ☐ Current reformed smoker (duration not specified) ☐ Current reformed smoker for >15 years ☐ Current reformed smoker for ≤15 years	2181650	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories.
15	Metastasis at diagnosis assessment status	☐ Metastatic ☐ Non-metastatic (confirmed) ☐ Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor. ***Note: If metastatic at diagnosis, proceed to Question 16, otherwise, skip to Question 17.***
16	Metastatic site(s) at diagnosis	☐ Bone ☐ Bone marrow ☐ Lymph nodes (regional) ☐ Lymph nodes (distant) ☐ Other (specify)	4616511	Indicate the site(s) of metastasis at the time of diagnosis of the primary tumor. ***Note: If the anatomic site of tumor tissue is not listed, proceed to Question 16a, otherwise, skip to Question 17.***
16a	Specify metastatic site	_____	3128033	If the site(s) of metastasis at the time of diagnosis of the primary tumor is not included in the provided list, specify the site(s).
Biospecimen Information				
17	Tissue sample type(s) collected for HCMI for this case	☐ Normal tissue ☐ Primary tumor ☐ Metastatic ☐ Recurrent ☐ Other tissue	2006911	Please select all the tissue sample types submitted for HCMI with this case.
18	Number of NORMAL tissues biospecimens collected for HCMI for this case	_____	6584256	Please provide the number of normal tissue specimens obtained for HCMI for this case. ***Note: This number is expected to be 1.***
19	Number of PRIMARY cancer tissue biospecimens collected for HCMI model development for this case	_____	6584257	Please provide the number of primary tumor specimens obtained for HCMI for this case. ***Note: A single primary tumor biospecimen obtained that is portioned for both sequencing and model generation counts as 1 single primary tumor specimen. This number is expected to be 1.***
20	Number of METASTATIC/ RECURRENT cancer tissue biospecimens collected for HCMI model development for this case	_____	6584258	Please provide the number of metastatic and/or recurrent cancer biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***



Enrollment: Neuroblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
21	Number of OTHER tissue biospecimens collected for HCMI model development for this case	_____	6584259	Please provide the number of pre-malignant, non-malignant, or dysplastic tissue biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
22	Total number of tissue biospecimens collected for HCMI for this case	_____	6584271	Please provide the total number of tissue biospecimens collected for HCMI for this case. ***Note: This number should be the sum of the normal, primary tumor, metastatic/ recurrent tumor, and other biospecimen counts above.***
Normal Control Information				
23	Normal tissue biospecimen ordinal	_____	6584264	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number is expected to be "1".***
24	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
25	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
26	Type of normal control	☐ Whole blood ☐ Buccal cells ☐ Buffy coat ☐ Lymphocytes ☐ Extracted DNA from blood ☐ Extracted DNA from saliva ☐ Extracted DNA from buccal cells ☐ Extracted DNA from normal tissue ☐ FFPE non-neoplastic tissue ☐ Non-neoplastic tissue	3081936	Indicate the type of normal control submitted for this case.
27	Anatomic site of normal tissue	☐ Skin ☐ Abdomen ☐ Adrenal gland ☐ Kidney ☐ Other (specify) ☐ Not applicable	4132152	If non-neoplastic tissue was submitted as the normal control, select the anatomic site of the normal tissue. ***Note: If the anatomic site of normal tissue is not listed, proceed to Question 27a, otherwise, skip to Question 28.***
27a	Other anatomic site of normal tissue	_____	3288189	If non-neoplastic tissue, adjacent tissue, or normal tissue from another anatomic site was submitted as the normal control, provide the anatomic site of the normal tissue.
28	Distance from tumor to normal control tissue (if not blood)	☐ Adjacent (< or = 2cm) ☐ Distal (>2cm) ☐ Unknown ☐ Not applicable	3088708	Indicate the distance from the site of normal tumor collection to the primary tumor. ***Note: If normal tissue was not submitted, select 'Not applicable'.***
29	Normal tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the normal tissue sample collected for molecular characterization.
Primary Tumor Biospecimen Information				
30	ICD-10 code for primary tumor	☐ 30.0 ☐ 74.9 ☐ 72.2 ☐ Other (specify)	3226287	Provide the ICD-10 code for the primary tumor as used to generate the ID3 for this subject. ***Note: If the ICD-10 code is not listed, proceed to 30a, otherwise, skip to Question 31.***



Enrollment: Neuroblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
30a	Other ICD-10 code for primary tumor	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.
31	Tumor morphology	☐ 9490/3 (Ganglioneuroblastoma) ☐ 9500/3 (Neuroblastoma, NOS) ☐ 9504/3 (Spongioneuroblastoma) ☐ 9522/3 (Olfactory neuroblastoma) ☐ Other (specify)	3226275	Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor. ***Note: If the ICD-O-3 histology code of the primary tumor is not listed, proceed to Question 31a, otherwise, skip to Question 32.***
31a	Other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.
32	Tissue or organ of origin	☐ Adrenal gland ☐ Extra-adrenal ☐ Other (specify)	3427536	Using the patient's pathology/laboratory report, select the primary site of the disease. ***Note: If the tissue or organ of origin is not listed, proceed to Question 32a, otherwise, skip to Question 33.***
32a	Other tissue or organ of origin	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	3427536	If the primary site of the disease is not included on the previous list, select the primary site of the disease.
33	Histological type	_____	3294805	Provide the traditional surgical pathology text description of the histological tumor type.
34	Histology	☐ Favorable ☐ Unfavorable ☐ Unknown	4616372	Using the patient's pathology/laboratory report, select the histology of the tumor submitted to the HCMI.



Enrollment: Neuroblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
35	Prior malignancy (of the same cancer type)	☐ Yes ☐ No ☐ Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
36	Prior malignancy (other cancer type)	☐ Yes ☐ No ☐ Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.
37	International Neuroblastoma Risk Group classification system stage	☐ L1 ☐ L2 ☐ M ☐ MS	5777238	Indicate the patient's INRG stage.
38	INSS stage	☐ Stage 1 ☐ Stage 2A ☐ Stage 2B ☐ Stage 3 ☐ Stage 4 ☐ Stage 4S ☐ Unknown	2974055	Indicate the patient's International Neuroblastoma Staging System disease stage.
39	COG risk classification	☐ Low risk ☐ Intermediate risk ☐ High risk ☐ Unknown	4616452	Indicate the patient's risk classification according to the Children's Oncology Group (COG).
40	INPC grade of neuroblastic differentiation	☐ Undifferentiated ☐ Poorly differentiated ☐ Differentiating ☐ Unknown	4616392	Indicate the grade of neuroblastic differentiation according to the revised International Neuroblastoma Pathology Classification (INPC).
41	Is necrosis present?	☐ Yes ☐ No ☐ Unknown	64740	Indicate whether necrosis was present in the primary tumor.
42	MYCN gene amplification status	☐ Amplified ☐ Not amplified ☐ Not done ☐ Unknown	4616052	Indicate the amplification status of the MYCN gene.
43	DNA ploidy analysis by flow cytometry	☐ Diploid (DI=1) ☐ Hyperdiploid (DI>1) ☐ Unknown	4616354	Select the DNA ploidy analysis by flow cytometry test result. ***Note: If DNA ploidy was hyperdiploid, proceed to Question 44, otherwise, skip to Question 45.***
44	DNA ploidy analysis by flow cytometry result value	_____	4824055	Specify the numerical result of the DNA ploidy analysis by flow cytometry.
45	INPC mitosis karyorrhexis index	☐ Low ☐ Intermediate ☐ High ☐ Unknown	4616412	Indicate the mitosis karyorrhexis index category according to the revised International Neuroblastoma Pathology Classification (INPC).
46	Was ALK mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	3773874	Indicate whether ALK mutation status was assessed. ***Note: If ALK mutation analysis was not performed, skip to Question 49.***
47	Was a mutation in ALK identified?	☐ Yes ☐ No	3774202	Indicate whether a mutation in ALK was identified. ***Note: If an ALK mutation was not identified, skip to Question 49.***
48	If ALK mutation identified, which one?	☐ F1174C ☐ F1174L ☐ F1174V ☐ F1245L ☐ K1062M ☐ R1275Q ☐ T1087I ☐ Other (specify)	6060279	If ALK mutation identified, which one? ***Note: If the ALK mutation is not listed, proceed to Question 48a, otherwise, skip to Question 49.***



Enrollment: Neuroblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
48a	Other ALK mutation	_____	6101680	If the ALK mutation identified is not included in the provided list, specify the ALK mutation identified.
Primary Tumor Sample Information				
49	Are you submitting a primary tumor tissue sample for this case?	☐ Yes ☐ No		***If yes, proceed to question 50.*** ***If submitting a metastatic/recurrent tumor biospecimen, proceed to Question 75.***
50	Primary tumor biospecimen ordinal	_____	6584265	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
51	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
52	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
53	Sample represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this primary tumor specimen represent the PRIMARY DIAGNOSIS for this Case ID3? ***Note: If no, continue to Question 54, otherwise, skip to Question 55.***
54	Specify the ICD-10 code	_____	3226287	Provide the ICD-10 code for the primary tumor used to generate the model submitted to HCMI.
55	Tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the tumor tissue sample collected for molecular characterization.
56	Anatomic site from which the tumor was obtained	☐ Abdominal/non-adrenal ☐ Adrenal ☐ Ascites ☐ Bone ☐ Bone marrow ☐ Extra-adrenal ☐ Lung ☐ Lymph node ☐ Neck ☐ Posterior mediastinum ☐ Other (specify)	5807222	Indicate the anatomic site of the tumor tissue used to generate the model for the HCMI. ***Note: If the anatomic site of the primary tumor tissue is not listed, proceed to Question 56a, otherwise, skip to Question 57.***
56a	Other anatomic site from which the tumor was obtained	_____	5946219	Provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.
57	Method of cancer sample procurement	☐ Core needle biopsy ☐ Excisional biopsy ☐ Fine needle aspiration ☐ Incisional biopsy ☐ Tumor resection ☐ Other (specify)	3103514	Indicate the procedure performed to obtain the tumor tissue used to generate the model for HCMI. ***Note: If the method of sample procurement is not listed, proceed to Question 57a, otherwise, skip to Question 58.***
57a	Other method of sample procurement	_____	2006730	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
58	Number of days from index date to date of cancer sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the tumor tissue submitted for HCMI.



Enrollment: Neuroblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
59	Tumor tissue type	☐ Primary ☐ Additional primary ☐ NOS	3288124	Provide the primary tumor tissue type for this sample.
Primary Tumor Model Information				
60	Primary model biospecimen ordinal	_____	6594596	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number is expected to be "1".***
61	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
62	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
63	Model represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this MODEL represent the PRIMARY DIAGNOSIS for this Case ID3?
64	Model's primary tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the PRIMARY TUMOR TISSUE from which this model is derived.
65	Model's primary tumor biospecimen ordinal	_____	6584265	Enter the biospecimen ordinal of the PRIMARY TUMOR TISSUE from which this model is derived.
Treatment Information				
66	History of neoadjuvant treatment	☐ No ☐ Yes; radiation prior to resection ☐ Yes; pharmaceutical treatment prior to resection ☐ Yes; both radiation and pharmaceutical treatment prior to resection ☐ Unknown	3382737	Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment. ***Note: Pharmaceutical therapy is addressed in Questions 67-73. Radiation therapy is addressed in Questions 74-75.***
67	Neoadjuvant chemotherapy type	☐ Cytotoxic chemotherapy ☐ Hormonal ☐ Immunotherapy (cellular and immune checkpoint) ☐ Targeted therapy (small molecule inhibitors and targeted antibodies) ☐ Not applicable	5832928	Select all neoadjuvant chemotherapy types that were administered to the patient. ***Note: Cytotoxic chemotherapy is addressed in Questions 68-69. Immunotherapy is addressed in Questions 70-71. Targeted therapy is addressed in Questions 72-73.***
68	Neoadjuvant chemotherapeutic regimen	☐ Busulfan and Melphalan ☐ Carboplatin ☐ Cis-retinoic acid ☐ Cisplatin ☐ Cyclophosphamide ☐ Doxorubicin ☐ Etoposide ☐ Ifosfamide ☐ Topotecan ☐ Vincristine ☐ Vincristine, actinomycin-D, cyclophosphamide (VAC) ☐ Vincristine, doxorubicin, cyclophosphamide, ifosfamide, etoposide (VDC/IE) ☐ Vincristine, actinomycin-D, cyclophosphamide, vincristine, irinotecan (VAC/VI) ☐ Ifosfamide, carboplatin, etoposide (ICE)	2853313	Select all chemotherapeutics used for neoadjuvant therapy. ***Note: If neoadjuvant chemotherapy was not given, skip to Question 70. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 68a, otherwise, skip to Question 69.***



Enrollment: Neuroblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

		☐ Vincristine, irinotecan, temozolomide (VIT) ☐ High-dose methotrexate, doxorubicin, cisplatin (MAP) ☐ Other (specify) ☐ Chemotherapy not given		
68a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapy.
69	Days to neoadjuvant chemotherapy treatment from index date	_____	5102411	Provide the number of days from index date to the date of treatment with neoadjuvant chemotherapy.
70	Immunotherapy	☐ Dinutuximab ☐ Other (specify)	6010528	Select the immunotherapy administered to the patient. ***Note: If the immunotherapy is not listed, proceed to Question 70a, otherwise, skip to Question 71.***
70a	Other immunotherapy	_____	2953828	Provide the name of the immunotherapy administered to the patient.
71	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
72	Targeted therapy	☐ ALK inhibitor ☐ MIBG ☐ Other (specify)	6010389	Select the targeted therapy administered to the patient. ***Note: If targeted therapy was not administered, skip to Question 74. If the targeted therapy is not listed, proceed to Question 72a, otherwise, skip to Question 73.***
72a	Other targeted therapy	_____	4308476	If the targeted therapy is not included in the provided list, specify targeted therapy.
73	Days to targeted therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with targeted therapy.
74	Radiation therapy administered type	☐ 2D conventional ☐ 3D conformal ☐ Brachytherapy HDR ☐ Brachytherapy LDR ☐ IMRT ☐ Proton Beam ☐ Stereotactic Body RT ☐ Stereotactic Radiosurgery ☐ WBRT ☐ Other (specify) ☐ Unspecified ☐ Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. ***Note: If radiation therapy was not administered, skip to Question 76. If the radiation therapy is not listed, proceed to Question 74a, otherwise, skip to Question 75.***
74a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
75	Days to radiation treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with radiation therapy.
Metastatic/Recurrent Tumor Biospecimen Information				
76	Are you submitting a metastatic/ recurrent tumor tissue sample?	☐ Yes ☐ No		Indicate whether a metastatic/recurrent tumor biospecimen was collected for this ID3 case. ***Note: If yes, proceed to Question 77. If submitting an OTHER tissue sample, proceed to Question 143.***



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
77	Metastatic/ recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1", the second should be number "2", etc.***
78	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
79	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
80	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
81	Number of days from index date to date of diagnosis of metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic/recurrent disease.
82	Method of metastatic/ recurrent cancer sample procurement	☐ Core needle biopsy ☐ Excisional biopsy ☐ Fine needle aspiration ☐ Incisional biopsy ☐ Tumor resection ☐ Other method, specify	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 82a, otherwise, skip to Question 83.***
82a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
83	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
84	Metastatic/ recurrent site	☐ Abdominal/non-adrenal ☐ Adrenal ☐ Ascites ☐ Bone ☐ Bone marrow ☐ Extra-adrenal ☐ Lung ☐ Lymph node(s) regional ☐ Lymph node(s) distant ☐ Neck ☐ Posterior mediastinum ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 84a, otherwise, skip to Question 85.***
84a	Other metastatic/ recurrent site	_____	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
85	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
86	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.



Enrollment: Neuroblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
87	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
88	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
89	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
90	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
91	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
92	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
93	International Neuroblastoma Risk Group classification system stage	☐ L1 ☐ L2 ☐ M ☐ MS	5777238	Indicate the patient's INRG stage.
94	INSS stage	☐ Stage 1 ☐ Stage 2A ☐ Stage 2B ☐ Stage 3 ☐ Stage 4 ☐ Stage 4S ☐ Unknown	2974055	Indicate the patient's International Neuroblastoma Staging System disease stage.
95	COG risk classification	☐ Low risk ☐ Intermediate risk ☐ High risk ☐ Unknown	4616452	Indicate the patient's risk classification according to the Children's Oncology Group (COG).
96	INPC grade of neuroblastic differentiation	☐ Undifferentiated ☐ Poorly differentiated ☐ Differentiating ☐ Unknown	4616392	Indicate the grade of neuroblastic differentiation according to the revised International Neuroblastoma Pathology Classification (INPC).
97	Is necrosis present?	☐ Yes ☐ No ☐ Unknown	64740	Indicate whether necrosis was present in the primary tumor.
98	MYCN gene amplification status	☐ Amplified ☐ Not amplified ☐ Not done ☐ Unknown	4616052	Indicate the amplification status of the MYCN gene.



Enrollment: Neuroblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
99	DNA ploidy analysis by flow cytometry	☐ Diploid (DI=1) ☐ Hyperdiploid (DI>1) ☐ Unknown	4616354	Select the DNA ploidy analysis by flow cytometry test result. ***Note: If DNA ploidy was hyperdiploid, proceed to Question 100, otherwise, skip to Question 101.***
100	DNA ploidy analysis by flow cytometry result value	_____	4824055	Specify the numerical result of the DNA ploidy analysis by flow cytometry.
101	INPC mitosis karyorrhexis index	☐ Low ☐ Intermediate ☐ High ☐ Unknown	4616412	Indicate the mitosis karyorrhexis index category according to the revised International Neuroblastoma Pathology Classification (INPC).
102	Was ALK mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	3773874	Indicate whether ALK mutation status was assessed. ***Note: If ALK mutation analysis was not performed, skip to Question 105.***
103	Was a mutation in ALK identified?	☐ Yes ☐ No	3774202	Indicate whether a mutation in ALK was identified. ***Note: If an ALK mutation was not identified, skip to Question 105.***
104	If ALK mutation identified, which one?	☐ F1174C ☐ F1174L ☐ F1174V ☐ F1245L ☐ K1062M ☐ R1275Q ☐ T1087I ☐ Other (specify)	6060279	If ALK mutation identified, which one? ***Note: If the ALK mutation is not listed, proceed to Question 104a, otherwise, skip to Question 105.***
104a	Other ALK mutation	_____	6101680	If the ALK mutation identified is not included in the provided list, specify the ALK mutation identified.
Additional Metastatic/Recurrent Tumor Biospecimen Information (if applicable)				
105	Are you submitting an additional metastatic/ recurrent tumor tissue sample?	☐ Yes ☐ No		A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen. ***Note: If yes, proceed to Question 106, otherwise, skip to Question 134.***
106	Metastatic/ recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. The first biospecimen should be number "1," the second should be number "2," etc.
107	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
108	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
109	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
110	Number of days from index date to date of diagnosis of metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic/recurrent disease.



Enrollment: Neuroblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
111	Method of metastatic/ recurrent cancer sample procurement	☐ Core needle biopsy ☐ Excisional biopsy ☐ Fine needle aspiration ☐ Incisional biopsy ☐ Tumor resection ☐ Other method, specify	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 111a, otherwise, skip to Question 112.***
111a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
112	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
113	Metastatic/ recurrent site	☐ Abdominal/non-adrenal ☐ Adrenal ☐ Ascites ☐ Bone ☐ Bone marrow ☐ Extra-adrenal ☐ Lung ☐ Lymph node(s) regional ☐ Lymph node(s) distant ☐ Neck ☐ Posterior mediastinum ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 113a, otherwise, skip to Question 114.***
113a	Other metastatic/ recurrent site	_____	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
114	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
115	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
116	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
117	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
118	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
119	Days to last known administration date of	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.



Enrollment: Neuroblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

	maintenance and/or consolidation therapy from index date			
120	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
121	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
122	International Neuroblastoma Risk Group classification system stage	☐ L1 ☐ L2 ☐ M ☐ MS	5777238	Indicate the patient's INRG stage.
123	INSS stage	☐ Stage 1 ☐ Stage 2A ☐ Stage 2B ☐ Stage 3 ☐ Stage 4 ☐ Stage 4S ☐ Unknown	2974055	Indicate the patient's International Neuroblastoma Staging System disease stage.
124	COG risk classification	☐ Low risk ☐ Intermediate risk ☐ High risk ☐ Unknown	4616452	Indicate the patient's risk classification according to the Children's Oncology Group (COG).
125	INPC grade of neuroblastic differentiation	☐ Undifferentiated ☐ Poorly differentiated ☐ Differentiating ☐ Unknown	4616392	Indicate the grade of neuroblastic differentiation according to the revised International Neuroblastoma Pathology Classification (INPC).
126	Is necrosis present?	☐ Yes ☐ No ☐ Unknown	64740	Indicate whether necrosis was present in the primary tumor.
127	MYCN gene amplification status	☐ Amplified ☐ Not amplified ☐ Not done ☐ Unknown	4616052	Indicate the amplification status of the MYCN gene.
128	DNA ploidy analysis by flow cytometry	☐ Diploid (DI=1) ☐ Hyperdiploid (DI>1) ☐ Unknown	4616354	Select the DNA ploidy analysis by flow cytometry test result. ***Note: If DNA ploidy was hyperdiploid, proceed to Question 129, otherwise, skip to Question 130.***
129	DNA ploidy analysis by flow cytometry result value	_____	4824055	Specify the numerical result of the DNA ploidy analysis by flow cytometry.
130	INPC mitosis karyorrhexis index	☐ Low ☐ Intermediate ☐ High ☐ Unknown	4616412	Indicate the mitosis karyorrhexis index category according to the revised International Neuroblastoma Pathology Classification (INPC).
131	Was ALK mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	3773874	Indicate whether ALK mutation status was assessed. ***Note: If ALK mutation analysis was not performed, skip to Question 134.***
132	Was a mutation in ALK identified?	☐ Yes ☐ No	3774202	Indicate whether a mutation in ALK was identified. ***Note: If an ALK mutation was not identified, skip to Question 134.***
133	If ALK mutation identified, which one?	☐ F1174C ☐ F1174L ☐ F1174V ☐ F1245L ☐ K1062M ☐ R1275Q ☐ T1087I ☐ Other (specify)	6060279	If ALK mutation identified, which one? ***Note: If the ALK mutation is not listed, proceed to Question 133a, otherwise, skip to Question 134.***



Enrollment: Neuroblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
133a	Other ALK mutation	_____	6101680	If the ALK mutation identified is not included in the provided list, specify the ALK mutation identified.
Metastatic/Recurrent Tumor Model Information				
134	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
135	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
136	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
137	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
138	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Additional Metastatic/Recurrent Biospecimen Tumor Model Information (if applicable)				
139	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
140	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
141	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
142	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
143	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Other Biospecimen Information				
144	Are you submitting an OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an OTHER tissue sample (e.g. pre-malignant, non-malignant, or dysplastic tissue, etc.) was collected for HCMI for this case. ***Note: If yes, proceed to Question 145.***



Enrollment: Neuroblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
145	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
146	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
147	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
148	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
149	Method of OTHER tissue sample procurement	☐ Core needle biopsy ☐ Excisional biopsy ☐ Fine needle aspiration ☐ Incisional biopsy ☐ Tumor resection ☐ Other method, specify	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 149a, otherwise, skip to Question 150.***
149a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
150	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
151	Tissue type	☐ Pre-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 151a, otherwise, skip to Question 152.***
151a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
152	Anatomic site of OTHER tissue	☐ Abdominal/non-adrenal ☐ Adrenal ☐ Ascites ☐ Bone ☐ Bone marrow ☐ Extra-adrenal ☐ Lung ☐ Lymph node(s) regional ☐ Lymph node(s) distant ☐ Neck ☐ Posterior mediastinum ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 152a, otherwise, skip to Question 153.***
152a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.
153	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
154	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.



Enrollment: Neuroblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Additional OTHER biospecimen Information (if applicable)				
155	Are you submitting an additional OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an additional OTHER tissue sample (pre-malignant, non-malignant, or dysplastic tissue, etc.) is being submitted for HCMI for this case. ***Note: If yes, proceed to Question 156, otherwise, skip to Question 166.***
156	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
157	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
158	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
159	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
160	Method of OTHER tissue sample procurement	☐ Core needle biopsy ☐ Excisional biopsy ☐ Fine needle aspiration ☐ Incisional biopsy ☐ Tumor resection ☐ Other method, specify	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 160a, otherwise, skip to Question 161.***
160a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
161	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
162	Tissue type	☐ Pre-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 162a, otherwise, skip to Question 163.***
162a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
163	Anatomic site of OTHER tissue	☐ Abdominal/non-adrenal ☐ Adrenal ☐ Ascites ☐ Bone ☐ Bone marrow ☐ Extra-adrenal ☐ Lung ☐ Lymph node(s) regional ☐ Lymph node(s) distant ☐ Neck ☐ Posterior mediastinum ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 163a, otherwise, skip to Question 164.***
163a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.



Enrollment: Neuroblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
164	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
165	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Other Tissue Model Information				
166	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
167	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
168	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
169	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
170	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.
Additional Other Tissue Model Information (if applicable)				
171	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
172	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
173	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
174	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.



Enrollment: Neuroendocrine Supplement

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Form Notes: A Neuroendocrine Supplement Enrollment Form should be completed for each HCMI neuroendocrine tumor case upon qualification notice from Leidos. The Neuroendocrine Supplement Enrollment form should be completed for each tissue sample that is classified as a neuroendocrine tumor.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
4	Indicate whether Ki-67 staining was performed?	☐ Yes ☐ No ☐ Unknown	5653372	Indicate whether Ki-67 staining was performed. ***Note: If Ki-67 staining was performed, proceed to Question 5, otherwise, skip to Question 8.***
5	Number of Ki-67 nuclear positive stained cells	_____	3235077	Indicate the number of Ki-67 nuclear positive stained cells.
6	Total cells counted	_____	3235081	Indicate the total number of cell counted.
7	Ki-67 percent nuclei	_____%	2842564	Indicate the percentage Ki-67 nuclear positive stained cells.
8	Number of mitoses?	_____	7069579	Indicate the number of mitoses.
9	Total area	_____	7069580	Indicate the surface area in mm^2 where mitoses were counted.
10	Neuroendocrine tumor histopathologic grade	☐ Low grade ☐ Intermediate grade ☐ High grade	4614617	Indicate the histopathologic grade of the neuroendocrine tissue sample.
11	Chromogranin A value	_____ng/mL	2500950	Indicate the Chromogranin A tumor marker test result measured in ng/mL.
12	Chromogranin B value	_____ng/mL	7069581	Indicate the Chromogranin B tumor marker test result measured in ng/mL.
13	Urinary 5HIAA value	_____mg/24 hour	2501274	Indicate the 5-Hydroxyindoleacetic Acid tumor marker result value in mg per 24 hour.
14	Neuron-specific enolase (NSE) value	_____mcg/L	2501111	Indicate the Neuron-Specific Enolase Tumor Marker result value in mcg per liter.
15	Neuroendocrine functional tumor status	☐ Cannot be assessed ☐ Functional ☐ Nonfunctional ☐ Functional status unknown	6941879	Indicate the neuroendocrine functional tumor status.
16	Indicate the functional type of neuroendocrine tumor	☐ Insulin-producing (insulinoma) ☐ Glucagon-producing (glucagonoma) ☐ Somatostatin-producing (somatostatinoma) ☐ Gastrin-producing (gastrinoma) ☐ Vasoactive intestinal polypeptide (VIP)-producing (VIPoma) ☐ Serotonin-producing (carcinoid) ☐ Other (specify)	6941881	Indicate the functional type of neuroendocrine tumor. ***Note: If the functional type is not listed, proceed to Question 16a, otherwise, skip to Question 17.***



Enrollment: Neuroendocrine Supplement

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
16a	Specify the other functional type of neuroendocrine tumor	_____	6941882	If the functional type of neuroendocrine tumor present is not included on the previous list, provide the functional type of neuroendocrine tumor present.
17	Was Chromogranin A IHC performed?	☐ Yes ☐ No ☐ Unknown	7069582	Indicate whether Chromogranin A expression was assessed by immunohistochemistry (IHC). ***Note: If Chromogranin A IHC was performed, proceed to Question 18, otherwise, skip to Question 19.***
18	Chromogranin A expression by IHC	☐ Positive ☐ Negative ☐ Intermediate ☐ Not done	7069583	Indicate the status of Chromogranin A protein expression as determined by immunohistochemistry (IHC).
19	Was Synaptophysin IHC performed?	☐ Yes ☐ No ☐ Unknown	7069584	Indicate whether Synaptophysin expression was assessed by immunohistochemistry (IHC). ***Note: If Synaptophysin IHC was performed, proceed to Question 20, otherwise, skip to Question 21.***
20	Synaptophysin expression by IHC	☐ Positive ☐ Negative ☐ Intermediate ☐ Not done	5243435	Indicate the status of Synaptophysin protein expression as determined by immunohistochemistry (IHC).
21	Was NCAM/CD56 IHC performed?	☐ Yes ☐ No ☐ Unknown	7069585	Indicate whether NCAM/CD56 expression was assessed by immunohistochemistry (IHC). ***Note: If NCAM/CD56 IHC was performed, proceed to Question 22, otherwise, skip to Question 23.***
22	NCAM/CD56 expression by IHC	☐ Positive ☐ Negative ☐ Intermediate ☐ Not done	7069586	Indicate the status of NCAM/CD56 protein expression as determined by immunohistochemistry (IHC).
23	Was CDX-2 IHC performed?	☐ Yes ☐ No ☐ Unknown	6690715	Indicate whether CDX-2 expression was assessed by immunohistochemistry (IHC). ***Note: If CDX-2 IHC was performed, proceed to Question 24, otherwise, skip to Question 25.***
24	CDX-2 expression by IHC	☐ Positive ☐ Negative ☐ Intermediate ☐ Not done	6690732	Indicate the status of CDX-2 protein expression as determined by immunohistochemistry (IHC).
25	Was TTF-1 IHC performed?	☐ Yes ☐ No ☐ Unknown	7069588	Indicate whether TTF-1 expression was assessed by immunohistochemistry (IHC). ***Note: If TTF-1 IHC was performed, proceed to Question 26.***
26	TTF-1 expression by IHC	☐ Positive ☐ Negative ☐ Intermediate ☐ Not done	7069587	Indicate the status of TTF-1 protein expression as determined by immunohistochemistry (IHC).



Enrollment: Osteosarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Form Notes: An Enrollment Form should be completed for each HCMI case upon qualification notice from Leidos. All information provided on this form should include activity from the Date of Initial Pathologic Diagnosis to the most recent Date of Last Contact with the patient.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	☐ Initial pathologic diagnosis ☐ Sample procurement ☐ First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.
Normal Control Information				
4	Type of normal control	☐ Whole blood ☐ Buccal cells ☐ Buffy coat ☐ Lymphocytes ☐ Extracted DNA from blood ☐ Extracted DNA from saliva ☐ Extracted DNA from buccal cells ☐ Extracted DNA from normal tissue ☐ FFPE non-neoplastic tissue ☐ Non-neoplastic tissue	3081936	Indicate the type of normal control submitted for this case.
Tumor Tissue Collected for Molecular Characterization, Sample Information				
5	Tumor tissue sample preservation method	☐ FFPE ☐ Fresh ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the tumor tissue sample collected to be used for molecular characterization.
Cancer Model Information				
6	Anatomic site of tumor from which model was derived	☐ Ascites ☐ Bone ☐ Lower extremity ☐ Lung ☐ Lymph node ☐ Mediastinum ☐ Pelvis ☐ Pleura ☐ Spine ☐ Upper extremity ☐ Other (specify)	6005095	Indicate the anatomic site of the tumor tissue used to generate the model for the HCMI. ***Note: If the anatomic site of tumor tissue is not listed, proceed to Question 6a, otherwise, skip to Question 7.***
6a	Other anatomic site	_____	5946219	If the anatomic site for the tumor submitted to HCMI is not included on the provided list, specify the anatomic site.
7	Method of cancer sample procurement	☐ Core needle biopsy ☐ Excisional biopsy ☐ Fine needle aspiration ☐ Incisional biopsy ☐ Tumor resection ☐ Other (specify)	3103514	Indicate the procedure performed to obtain the tumor tissue used to generate the model for HCMI. ***Note: If the method of sample procurement is not listed, proceed to Question 7a, otherwise, skip to Question 8.***
7a	Other method of sample procurement	_____	2006730	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
8	Number of days from index date to date of cancer sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the tumor tissue submitted for HCMI.



Enrollment: Osteosarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
9	ICD-10 code for model tumor	☐ C40.0 ☐ C41.3 ☐ C40.1 ☐ C41.4 ☐ C40.2 ☐ C41.8 ☐ C40.3 ☐ C41.9 ☐ C40.8 ☐ C77.9 ☐ C40.9 ☐ C78.0 ☐ C41.0 ☐ C78.1 ☐ C41.1 ☐ C79.5 ☐ C41.2 ☐ Other (specify)	3226287	Provide the ICD-10 code for the tumor used to generate the model submitted to HCMI. ***Note: If the ICD-10 code is not listed, proceed to Question 9a, otherwise, skip to Question 10.***
9a	Other ICD-10 code	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.
10	Tumor tissue type	☐ Premalignant ☐ Primary ☐ Recurrent ☐ Metastatic ☐ Additional primary ☐ NOS	3288124	Provide the tumor tissue type for the biospecimen used to produce the model for the HCMI. ***Note: If 'Metastatic' is selected, continue to answer through Question 18. If the tissue is not 'Metastatic', skip to Question 19.***
Metastatic Model Information *(only complete Questions 11-18 if 'Metastatic' was selected in Question 10)*				
11	Age at diagnosis of metastasis	_____	6032752	Provide the age (in days) of the patient when diagnosed with metastatic disease. If the patient's age is greater than 32,507 days (89 years), please enter 32,507.
12	Number of days from index date to date of diagnosis of metastasis	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic disease.
13	Metastatic site	☐ Lung ☐ Bone ☐ Mediastinum ☐ Lymph node (not mediastinum) ☐ Other (specify)	6119068	Select the site from which the metastatic tissue used to develop the model was derived. ***Note: If the metastatic site is not listed, proceed to Question 13a, otherwise, skip to Question 14.***
13a	Other metastatic site	_____	3128033	If not included in the previous list, specify the site from which the metastatic tissue used to develop the model was derived.
14	Maintenance and/or consolidation therapy administered prior to collection of metastatic tissue	_____	6119066	If applicable, provide the name of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic tissue used to develop the model. ***Note: If maintenance and/or consolidation therapy was not administered, skip to Question 19.***
15	Days from index date to start of maintenance and/or consolidation therapy	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
16	Days from index date to last known date of maintenance and/or consolidation therapy treatment	_____	65167	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.



Enrollment: Osteosarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
17	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing treatment.
18	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
Patient Information				
19	Gender	☐ Male ☐ Female ☐ Unspecified	2200604	Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
20	Height	_____	649	Provide the patient's height, in centimeters.
21	Weight	_____	651	Provide the patient's weight, in kilograms.
22	Body mass index (BMI)	_____	2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
23	Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown ☐ Not allowed to collect	2192199	Provide the patient's race using the defined categories. **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 peoples of the Far East, Southeast Asia, or in the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Phillippine Islands, Thailand, and Vietnam. **Black or African American:** A person having origins in any of the black racial groups of Africa. **Native Hawaiian or other Pacific Islander:** A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island. **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
24	Ethnicity	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Not allowed to collect	2192217	Provide the patient's ethnicity using the defined categories. **Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. **Not Hispanic or Latino:** A person not meeting the definition of Hispanic or Latino.
25	Year of birth	_____	2896954	Provide the year of the patient's birth. If the patient was born prior to 1928, insert the date 1928.
26	Family history of cancer	☐ Same ☐ Different ☐ None ☐ Unknown	5832923	Has a first-degree relative of the patient been diagnosed with a cancer of the same or a different type?
27	Tobacco smoking history	☐ Lifelong non-smoker (<100 cigarettes smoked in a lifetime) ☐ Current smoker (includes daily and non-daily smokers) ☐ Current reformed smoker (duration not specified) ☐ Current reformed smoker for >15 years ☐ Current reformed smoker for ≤15 years	2181650	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories.



Enrollment: Osteosarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Primary Tumor Diagnosis Information				
28	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.
29	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. If the patient's age is greater than 32,507 days (89 years), please enter 32,507.
30	Morphology	☐ 9180/3 (Osteosarcoma, NOS) ☐ 9181/3 (Chondroblastic osteosarcoma) ☐ 9182/3 (Fibroblastic osteosarcoma) ☐ 9183/3 (Telangiectatic osteosarcoma) ☐ 9184/3 (Osteosarcoma in Paget disease of bone) ☐ 9185/3 (Small cell osteosarcoma) ☐ 9186/3 (Central osteosarcoma) ☐ 9187/3 (Intraosseous well differentiated osteosarcoma) ☐ 9192/3 (Parosteal osteosarcoma) ☐ 9193/3 (Periosteal osteosarcoma) ☐ 9194/3 (High grade surface osteosarcoma) ☐ 9195/3 (Intracortical osteosarcoma) ☐ Other (specify)	3226275	Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor. ***Note: If the morphology is not listed, proceed to Question 30a, otherwise, skip to Question 31.***
30a	Other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.
31	Tissue or organ of origin	☐ Limb ☐ Pelvis ☐ Spine ☐ Other (specify)	3427536	Using the patient's pathology/laboratory report, select the primary site of the disease. ***Note: If the tissue or organ of origin is not listed, proceed to Question 31a, otherwise, skip to Question 32.***



Enrollment: Osteosarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
31a	Other tissue or organ of origin	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	3427536	If the primary site of the disease is not included on the previous list, select the primary site of the disease.
32	Histological type	☐ Malignant bone neoplasm ☐ Other (specify)	3081932	Provide the traditional surgical pathology text description of the histological tumor type. ***Note: If the histological type is not listed, proceed to Question 32a, otherwise, skip to Question 33.***
32a	Other histological type	_____	3294805	If the traditional surgical pathology text description of the histological tumor type is not included on the previous list, please specify the histological type.
33	Histological subtype	☐ Osteoblastic ☐ Chondroblastic ☐ Fibroblastic ☐ Telangiectatic ☐ Unknown	4214626	Using the patient's pathology/laboratory report, select the histological subtype of the primary tumor.
34	Prior malignancy (of the same cancer type)	☐ Yes ☐ No ☐ Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
35	Prior malignancy (other cancer type)	☐ Yes ☐ No ☐ Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.



Enrollment: Osteosarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
36	Osteosarcoma stage	☐ Localized ☐ Certain metastatic ☐ Possible metastatic ☐ Unknown	4928400	Provide the stage of the tumor using the COG Osteosarcoma staging guidelines.
37	Primary tumor size (largest dimension, in cm)	_____	64215	Provide the length of the largest dimension of the primary tumor, in centimeters.
38	Percent tumor necrosis	_____	2841237	Indicate the percent necrosis of the primary tumor at the time of resection.
39	Metastasis at diagnosis assessment status	☐ Metastatic ☐ Non-metastatic (confirmed) ☐ Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor.
40	Metastatic site(s) at diagnosis	☐ Lung ☐ Bone ☐ Mediastinum ☐ Lymph node (not mediastinum) ☐ Other (specify)	4616511	Indicate all the site(s) of metastasis at the time of diagnosis of the primary tumor. ***Note: If the metastatic site(s) is not listed, proceed to Question 39a, otherwise, skip to Question 40.***
40a	Specify metastatic site(s)	_____	3128033	If the site(s) of metastasis at the time of diagnosis of the primary tumor is not included in the provided list, specify the site(s).
41	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, select all sites of relapse. ***Note: If the primary tumor did not relapse, select 'Not applicable'.***
Prognostic/Predictive/Lifestyle Features for Tumor Prognosis or Responsiveness to Treatment				
42	Enneking/MSTS stage; Grade	☐ Low grade (G1) ☐ High grade (G2) ☐ Unknown	6003955	Provide the grade of the primary tumor according to the Enneking Musculoskeletal Tumor Society (MSTS) staging system.
43	Enneking/MSTS stage; Tumor	☐ Intracompartmental (T1) ☐ Extracompartmental (T2) ☐ Unknown	6003957	Provide the tumor stage of the primary tumor according to the Enneking Musculoskeletal Tumor Society (MSTS) staging system.
44	Enneking/MSTS stage; Metastasis	☐ No metastasis (M0) ☐ Regional or distant metastasis (M1) ☐ Unknown	6003958	Provide the metastatic stage according to the Enneking Musculoskeletal Tumor Society (MSTS) staging system.
Treatment Information				
45	History of neoadjuvant treatment	☐ No ☐ Yes; radiation prior to resection ☐ Yes; pharmaceutical treatment prior to resection ☐ Yes; both radiation and pharmaceutical treatment prior to resection ☐ Unknown	3382737	Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment. ***Note: Radiation therapy is addressed in Questions 53-54. Pharmaceutical therapy is addressed in Questions 46-52.***
46	Neoadjuvant chemotherapy type	☐ Cytotoxic chemotherapy ☐ Hormonal ☐ Immunotherapy (cellular and immune checkpoint) ☐ Targeted therapy (small molecule inhibitors and targeted antibodies) ☐ Not applicable	5832928	Select all neoadjuvant chemotherapy types that were administered to the patient. ***Note: Cytotoxic chemotherapy is addressed in Questions 47-48. Immunotherapy is addressed in Questions 49-50. Targeted therapy is addressed in Questions 51-52.***



Enrollment: Osteosarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
47	Neoadjuvant chemotherapeutic regimen	☐ Cisplatin ☐ Docetaxel ☐ Doxorubicin ☐ Etoposide ☐ Ifosfamide ☐ Methotrexate ☐ Vincristine ☐ Vincristine, actinomycin-D, cyclophosphamide (VAC) ☐ Vincristine, doxorubicin, cyclophosphamide, ifosfamide, etoposide (VDC/IE) ☐ Vincristine, actinomycin-D, cyclophosphamide, vincristine, irinotecan (VAC/VI) ☐ Ifosfamide, carboplatin, etoposide (ICE) ☐ Vincristine, irinotecan, temozolomide (VIT) ☐ High-dose methotrexate, doxorubicin, cisplatin (MAP) ☐ Other (specify) ☐ Chemotherapy not given	2853313	Select all chemotherapeutics used for neoadjuvant therapy. ***Note: If neoadjuvant chemotherapy was not given, skip to Question 49. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 47a, otherwise, skip to Question 48.***
47a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapy.
48	Days to neoadjuvant chemotherapy treatment from index date	_____	5102411	Provide the number of days from index date to the date of treatment with neoadjuvant chemotherapy.
49	Immunotherapy name, specify	_____	2185614	Specify the name of the immunotherapy administered. ***Note: If immunotherapy was not given, skip to Question 51.***
50	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
51	Targeted molecular therapy name, specify	_____	2842797	Specify the targeted therapy administered to the patient. ***Note: If targeted therapy was not given, skip to Question 53.***
52	Days to targeted therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with targeted therapy.
53	Radiation therapy administered type	☐ 2D conventional ☐ 3D conformal ☐ Brachytherapy HDR ☐ Brachytherapy LDR ☐ IMRT ☐ Proton Beam ☐ Stereotactic Body RT ☐ Stereotactic Radiosurgery ☐ WBRT ☐ Other (specify) ☐ Unspecified ☐ Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. ***Note: If radiation therapy was not administered, skip the remaining questions. If the radiation therapy is not listed, proceed to Question 53a, otherwise, skip to Question 54.***



Enrollment: Osteosarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
53a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
54	Days to radiation treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with radiation therapy.



Enrollment: Ovarian

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Form Notes: An Enrollment Form should be completed for each HCMI case upon qualification notice from Leidos. All information provided on this form should include activity from the Date of Initial Pathologic Diagnosis to the most recent Date of Last Contact with the patient.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	☐ Initial pathologic diagnosis ☐ Sample procurement ☐ First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.
Patient Information				
4	Gender	☐ Male ☐ Female ☐ Unspecified	2200604	Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
5	Height	_____	649	Provide the patient's height, in centimeters.
6	Weight	_____	651	Provide the patient's weight, in kilograms.
7	Body mass index (BMI)	_____	2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
8	Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown ☐ Not reported	2192199	Provide the patient's race using the defined categories. **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 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. **Black or African American:** A person having origins in any of the black racial groups of Africa. **Native Hawaiian or other Pacific Islander:** A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island. **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
9	Ethnicity	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Not reported	2192217	Provide the patient's ethnicity using the defined categories. **Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. **Not Hispanic or Latino:** A person not meeting the definition of Hispanic or Latino.
10	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.



Enrollment: Ovarian

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
11	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. ***Note: If the patient's age is greater than 32,872 days (90 years), please enter 32,872.***
12	Year of birth	_____	2896954	Provide the year of the patient's birth. ***Note: If the patient was born prior to 1928, insert the date 1928.***
13	Family history of cancer	☐ Same ☐ Different ☐ None ☐ Unknown	5832923	Has a first-degree relative of the patient been diagnosed with a cancer of the same or a different type?
14	Smoking history	☐ Lifelong non-smoker (<100 cigarettes smoked in a lifetime) ☐ Current smoker (includes daily and non-daily smokers) ☐ Current reformed smoker (duration not specified) ☐ Current reformed smoker for >15 years ☐ Current reformed smoker for ≤15 years	2181650	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories.
15	Metastasis at diagnosis assessment status	☐ Metastatic ☐ Non-metastatic (confirmed) ☐ Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor. ***Note: If metastatic at diagnosis, proceed to Question 16, otherwise, skip to Question 17.***
16	Metastatic site(s) at diagnosis	☐ Liver ☐ Lung ☐ Peritoneum ☐ Omentum ☐ Pleura ☐ Lymph nodes ☐ Other (specify)	3029815	Indicate the site(s) of metastasis at the time of diagnosis of the primary tumor. ***Note: If the anatomic site of tumor tissue is not listed, proceed to Question 16a, otherwise, skip to Question 17.***
16a	Specify metastatic site(s)	_____	3128033	If the site of metastasis is not included on the provided list, specify the site of metastasis.
17	Clinical history	☐ BRCA1/2 family history ☐ Hereditary breast/ovarian cancer ☐ Lynch syndrome ☐ Not applicable ☐ Other (specify)	6690684	Indicate patient's prior relevant clinical history. ***Note: If no ovarian cancer risk factors have been identified, skip to Question 18. If the clinical history is not listed, proceed to Question 17a, otherwise, skip to Question 18.***
17a	Other clinical history	_____	6690685	If a disease or disorder in the patient's clinical history is not included in the provided list, please specify.
Biospecimen Information				
18	Tissue sample type(s) collected for HCMI for this case	☐ Normal tissue ☐ Primary tumor ☐ Metastatic ☐ Recurrent ☐ Other tissue	2006911	Please select all the tissue sample types submitted for HCMI with this case.
19	Number of NORMAL tissues biospecimens collected for HCMI for this case	_____	6584256	Please provide the number of normal tissue specimens obtained for HCMI for this case. ***Note: This number is expected to be 1.***
20	Number of PRIMARY cancer tissue biospecimens collected for HCMI model development for this case	_____	6584257	Please provide the number of primary tumor specimens obtained for HCMI for this case. ***Note: A single primary tumor biospecimen obtained that is portioned for both sequencing and model generation counts as 1 single primary tumor specimen. This number is expected to be 1.***



Enrollment: Ovarian

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
21	Number of METASTATIC/ RECURRENT cancer tissue biospecimens collected for HCMI model development for this case	_____	6584258	Please provide the number of metastatic and/or recurrent cancer biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
22	Number of OTHER tissue biospecimens collected for HCMI model development for this case	_____	6584259	Please provide the number of pre-malignant, non-malignant, or dysplastic tissue biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
23	Total number of tissue biospecimens collected for HCMI for this case	_____	6584271	Please provide the total number of tissue biospecimens collected for HCMI for this case. ***Note: This number should be the sum of the normal, primary tumor, metastatic/ recurrent tumor, and other biospecimen counts above.***
Normal Control Information				
24	Normal tissue biospecimen ordinal	_____	6584264	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
25	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
26	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
27	Type of normal control	☐ Whole blood ☐ Buccal cells ☐ Buffy coat ☐ Lymphocytes ☐ Extracted DNA from blood ☐ Extracted DNA from saliva ☐ Extracted DNA from buccal cells ☐ Extracted DNA from normal tissue ☐ FFPE non-neoplastic tissue ☐ Non-neoplastic tissue	3081936	Indicate the type of normal control submitted for this case.
28	Anatomic site of normal tissue	☐ Right ovary ☐ Left ovary ☐ Right fallopian tube ☐ Left fallopian tube ☐ Right tubo-ovarian ☐ Left tubo-ovarian ☐ Omentum ☐ Other (specify) ☐ Not applicable	4132152	If non-neoplastic tissue was submitted as the normal control, select the anatomic site of the normal tissue. ***Note: If the anatomic site of normal tissue is not listed, proceed to Question 28a, otherwise, skip to Question 29.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
28a	Other anatomic site of normal tissue	_____	3288189	If non-neoplastic tissue, adjacent tissue, or normal tissue from another anatomic site was submitted as the normal control, provide the anatomic site of the normal tissue.
29	Distance from tumor to normal control tissue (if not blood)	☐ Adjacent (< or = 2cm) ☐ Distal (>2cm) ☐ Unknown ☐ Not applicable	3088708	Indicate the distance from the site of normal tumor collection to the primary tumor. ***Note: If normal tissue was not submitted, select 'Not applicable'.***
30	Normal tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the normal tissue sample collected for molecular characterization.
Primary Tumor Biospecimen Information				
31	ICD-10 code for primary tumor	☐ C56.1 ☐ C56.2 ☐ C56.9 ☐ Other (specify)	3226287	Provide the ICD-10 code for the primary tumor as used to generate the ID3 for this subject. ***Note: If the ICD-10 code is not listed, proceed to 31a, otherwise, skip to Question 32.***
31a	Other ICD-10 code for primary tumor	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.
32	Tumor Morphology	☐ 8020/3 ☐ 8041/3 ☐ 8120/3 ☐ 8310/3 ☐ 8323/3 ☐ 8380/3 ☐ 8381/3 ☐ 8441/3 ☐ 8480/3 ☐ 8620/1 ☐ 8622/1 ☐ 8634/3 ☐ 8805/3 ☐ 8931/3 ☐ 8933/3 ☐ 8950/3 ☐ 9000/3 ☐ 9015/3 ☐ 9060/3 ☐ 9070/3 ☐ 9071/3 ☐ 9072/3 ☐ 9080/3 ☐ 9085/3 ☐ 9100/3 ☐ Other (specify)	3226275	Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor. ***Note: If the ICD-O-3 histology code of the primary tumor is not listed, proceed to Question 32a, otherwise, skip to Question 33.***
32a	Specify other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.
33	Tissue or organ of origin	☐ Ovary ☐ Other (specify)	3427536	Using the patient's pathology/laboratory report, select the primary site of the disease. ***Note: If the primary site of the disease is not listed, proceed to Question 33a, otherwise skip to Question 34.***
33a	Other tissue or organ of origin	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Brain ☐ Breast ☐ Colon ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Other ill-defined sites ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Rectum ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin	3427536	If the primary site of the disease is not included on the previous list, provide the primary site of the disease.



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		☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina Vulva Oropharynx		
34	Histological Type	☐ Ovarian cancer ☐ Other (specify)	3081932	Select the surgical pathology text description of the histological tumor type. ***Note: If the histological tumor type is not listed, proceed to Question 34a, otherwise, skip to Question 35.***
34a	Other histological type	_____	3294805	If the traditional surgical pathology text description of the histological tumor type is not included on the previous list, please specify the histological type.
35	Histological subtype	<u>Serous:</u> ☐ Serous tubal intraepithelial carcinoma (STIC) ☐ Serous borderline tumor/atypical proliferative serous tumor ☐ Serous borderline tumor/atypical proliferative serous tumor with microinvasion ☐ Serous borderline tumor-micropapillary variant/noninvasive low-grade serous carcinoma ☐ Low-grade serous carcinoma ☐ High grade serous carcinoma <u>Mucinous:</u> ☐ Mucinous borderline tumor/atypical proliferative serous tumor ☐ Mucinous borderline tumor/atypical proliferative mucinous tumor with intraepithelial carcinoma ☐ Mucinous borderline tumor/atypical proliferative mucinous tumor with microinvasion ☐ Mucinous carcinoma <u>Seromucinous:</u> ☐ Seromucinous borderline tumor/atypical proliferative seromucinous tumor ☐ Seromucinous borderline tumor/atypical proliferative seromucinous tumor with microinvasion ☐ Seromucinous carcinoma <u>Endometrioid:</u> ☐ Endometrioid borderline tumor/atypical proliferative endometrioid tumor	3081934	Using the patient's pathology/laboratory report, select the histological subtype of the primary tumor. ***Note: If the histological subtype is not listed, proceed to Question 35a, otherwise, skip to Question 36.***



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		☐ Endometrioid borderline tumor/atypical proliferative endometrioid tumor with microinvasion ☐ Endometrioid carcinoma <u>Clear Cell:</u> ☐ Clear cell borderline tumor/atypical proliferative clear cell tumor ☐ Clear cell carcinoma <u>Brenner:</u> ☐ Borderline Brenner tumor/atypical proliferative Brenner tumor ☐ Malignant Brenner tumor ☐ Mixed epithelial borderline tumor <u>Malignant Sex Cord-Stromal:</u> ☐ Granulosa cell tumor, adult type ☐ Granulosa cell tumor, juvenile type ☐ Sertoli-Leydig cell tumor ☐ Other sex cord-stromal tumor <u>Malignant Germ Cell:</u> ☐ Dysgerminoma ☐ Yolk sac tumor ☐ Embryonal carcinoma ☐ Choriocarcinoma, non-gestational ☐ Immature teratoma ☐ Carcinoma arising in a teratoma ☐ Mixed malignant germ cell tumor <u>Other:</u> ☐ Carcinoma, Subtype Cannot Be Determined ☐ Undifferentiated Carcinoma ☐ Carcinosarcoma (malignant mixed Müllerian tumor) ☐ Small cell carcinoma, pulmonary type ☐ Small cell carcinoma, hypercalcemic type ☐ Squamous cell carcinoma ☐ Transitional cell carcinoma ☐ Undifferentiated carcinoma ☐ Other (specify)		
35a	Other histological subtype	_____	3124492	If the histological subtype for the primary tumor is not included in the provided list, specify the histological subtype.
36	Prior malignancy (of the same cancer type)	☐ Yes ☐ No ☐ Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
37	Prior malignancy (other cancer type)	☐ Yes ☐ No ☐ Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.
38	AJCC cancer staging edition	☐ 1st ☐ 2nd ☐ 3rd ☐ 4th ☐ 5th ☐ 6th ☐ 7th ☐ 8th	2722309	Select the AJCC staging handbook edition used to stage the patient's primary tumor.
39	AJCC pathologic spread: Primary tumor (pT)	☐ TX ☐ T0 ☐ T1 ☐ T1a ☐ T1b ☐ T1c ☐ T1c1 ☐ T1c2 ☐ T1c3 ☐ T2 ☐ T2a ☐ T2b ☐ T3 ☐ T3a ☐ T3b ☐ T3c	3045435	Using the patient's pathology/laboratory report, select the code for the pathologic T (primary tumor) as defined by the American Joint Committee on Cancer (AJCC).
40	AJCC pathologic spread: Lymph nodes (pN)	☐ NX ☐ N0 ☐ N0(i+) ☐ N1 ☐ N1a ☐ N1b	3203106	Using the patient's pathology/laboratory report, select the code for the pathologic N (nodal) as defined by the American Joint Committee on Cancer (AJCC).



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
41	AJCC pathologic spread: Distant metastases (pM)	☐ MX ☐ M0 ☐ M1 ☐ M1a ☐ M1b	3045439	Using the patient's pathology/laboratory report, select the code for the pathologic M (metastasis) as defined by the American Joint Committee on Cancer (AJCC).
42	Tumor stage (pathological)	☐ Stage I ☐ Stage IA ☐ Stage IB ☐ Stage IC ☐ Stage II ☐ Stage IIA ☐ Stage IIB ☐ Stage IIIA1 ☐ Stage IIIA2 ☐ Stage IIIB ☐ Stage IIIC ☐ Stage IV ☐ Stage IVA ☐ Stage IVB	3065862	Using the patient's pathology/laboratory report, in conjunction with the patient's medical record, select the stage as defined by the American Joint Committee on Cancer (AJCC).
43	FIGO stage	☐ I ☐ IA ☐ IB ☐ IC ☐ IC1 ☐ IC2 ☐ IC3 ☐ II ☐ IIA ☐ IIB ☐ III ☐ IIIA ☐ IIIA1 ☐ IIIA1(i) ☐ IIIA1(ii) ☐ IIIA2 ☐ IIIB ☐ IIIC ☐ IV ☐ IVA ☐ IVB	5326898	Using the patient's pathology/laboratory report, in conjunction with the patient's medical record, select the stage as defined by the Federation of Gynecology and Obstetrics (FIGO), 2014 edition.
44	Two-tier grade	☐ Low grade ☐ High grade ☐ Not applicable	6690670	Using the patient's pathology/laboratory report, select the grade using the two-tier grading system. ***Note: This question is required for serous carcinomas.***
45	Tumor grade for immature teratomas	☐ G1 ☐ G2 ☐ G3 ☐ GX	2785839	Using the patient's pathology/laboratory report, if the primary tumor is an immature teratoma, select the grade.
46	Specimen integrity	☐ Capsule intact ☐ Capsule ruptured ☐ Fragmented ☐ Other (specify)	6690671	Select the best description of the physical condition of the ovarian cancer tumor. ***Note: If the specimen integrity is not listed, proceed to Question 46a, otherwise, skip to Question 47.***
46a	Specify specimen integrity	_____	6690672	If not included in the previous list, specify the best description of the physical condition of the ovarian cancer tumor.
47	Ovarian surface involvement	☐ Present ☐ Absent ☐ Cannot be determined	6690674	Indicate whether the surface tissue (outer boundary) of the ovary shows evidence of involvement or presence of cancer.
48	Tumor size, largest dimension	_____ cm	64215	Provide the largest dimension of the primary tumor in cm, regardless of anatomical plane.
49	Other tissue/organ involvement (select all that apply)	☐ Right ovary ☐ Left ovary ☐ Ovary (side not specified) ☐ Right fallopian tube ☐ Left fallopian tube ☐ Fallopian tube (side not specified) ☐ Uterus ☐ Cervix ☐ Pelvic peritoneum ☐ Abdominal peritoneum ☐ Omentum ☐ Not applicable ☐ Not identified ☐ Other (specify)	2793699	Select all sites of other tissue/organ involvement. This does not include the primary tumor site. ***Note: If the other tissue/organ involvement is not listed, proceed to Question 49a, otherwise, skip to Question 50.***
49a	Specify other tissue/organ involvement	_____	6690678	If not included in the previous list, specify the other site of other tissue/organ involvement. This does not include the primary tumor site.



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50	Largest extrapelvic peritoneal focus	☐ Microscopic ☐ Macroscopic (2 cm or less) ☐ Macroscopic (greater than 2 cm) ☐ Not applicable ☐ Cannot be determined	6690680	Indicate the diameter of the largest focus originating outside of the pelvic peritoneal region.
51	Peritoneal/Ascitic fluid	☐ Not submitted/unknown ☐ Negative for malignancy (normal/benign) ☐ Atypical and/or suspicious ☐ Malignant (positive for malignancy) ☐ Unsatisfactory/nondiagnostic	6690681	Indicate the outcome of cytological analysis for peritoneal/ascitic fluid.
52	Number of positive lymph nodes	_____	89	Provide the number of lymph nodes with disease involvement.
53	Number of lymph nodes examined	_____	3	Provide the total number of lymph nodes tested for the presence of cancer cells.
54	Additional pathologic findings	☐ None identified ☐ Serous tubal intraepithelial carcinoma (STIC) ☐ Endometriosis ☐ Endosalpingiosis ☐ Other (specify)	6690682	Indicate additional pathologic findings present in the patient. ***Note: If the additional pathologic finding is not listed, proceed to Question 54a, otherwise, skip to Question 55.***
54a	Specify additional pathologic findings	_____	6690683	If not included in the previous list, specify any additional pathologic findings.
55	Treatment effect	☐ CRS 1 ☐ CRS 2 ☐ CRS 3 ☐ No known presurgical therapy ☐ Cannot be determined	6692843	Select the original Chemotherapy Response Score that indicates the histopathologic response and prognosis of patients with tubo-ovarian high-grade serous carcinoma (HGSC) receiving neoadjuvant chemotherapy.
56	Was upper GI-endoscopy performed with negative results to exclude a gastrointestinal primary malignancy?	☐ Yes ☐ No ☐ Unknown	6690696	Indicate whether an upper gastrointestinal endoscopy was performed that excluded a gastrointestinal primary malignancy.
57	Was colonoscopy performed with negative results to exclude a gastrointestinal primary malignancy?	☐ Yes ☐ No ☐ Unknown	6690697	Indicate whether a colonoscopy was performed that excluded a gastrointestinal primary malignancy.
58	Residual tumor following surgical debulking	☐ No grossly visible tumor ☐ Residual tumor <= 1 cm ☐ Residual tumor > 1 cm	6690699	Indicate the status of a residual neoplasm following tumor debulking.
59	Was serum CA-125 measured?	☐ Yes ☐ No ☐ Unknown	6692833	Indicate whether a test of serum levels of CA-125 was performed. ***Note: If serum CA-125 was measured, proceed to Question 60, otherwise, skip to Question 64.***
60	Baseline CA-125 (at diagnosis, before neoadjuvant chemotherapy or surgery)	_____	6690700	Provide the numeric value of CA-125 at baseline.
61	CA-125 at the end of neoadjuvant chemotherapy	_____	6690702	Provide the numeric value of CA-125 at the end of neoadjuvant chemotherapy.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
62	CA-125 after debulking surgery	_____	6690704	Provide the numeric value of CA-125 following tumor debulking surgery.
63	CA-125 during follow-up/ at the time of recurrence	_____	3008730	Provide the numeric value of CA-125 at the time of follow-up or initial disease recurrence.
Primary Tumor Clinical Molecular Characterization				
64	Was BRCA1 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6690686	Indicate whether mutation analysis of BRCA1 was performed. ***Note: If BRCA1 mutation analysis was performed, proceed to Question 65, otherwise, skip to Question 69.***
65	BRCA1 mutational analysis result	☐ No variant ☐ Benign variant ☐ Pathogenic variant (specify) ☐ Variant of uncertain significance (VUS) (specify)	6690687	Indicate the type of BRCA1 variant identified as a result of mutational analysis. ***Note: If a pathogenic variant or variant of uncertain significance was identified, proceed to Question 65a, otherwise, skip to Question 66.***
65a	Specify the BRCA1 variant	_____	6690688	Specify the pathogenic BRCA1 variant or BRCA1 variant of unknown significance identified as a result of mutational analysis.
66	Method used to identify BRCA1 mutation	☐ Next-generation targeted sequencing ☐ Whole exome sequencing ☐ Cancer hotspot panel (specify) ☐ Other (specify)	6003729	Indicate the method used in BRCA1 mutation analysis. ***Note: If a cancer hotspot panel was used, proceed to Question 67. If the method is not listed, proceed to Question 68, otherwise skip to Question 69.***
67	Specify the panel sequencing test used to identify the BRCA1 mutation	_____	6690689	Specify the cancer hotspot panel used in BRCA1 mutation analysis.
68	Other method used to identify BRCA1 mutation	_____	6002204	If not included in the previous list, specify the method used in BRCA1 mutation analysis.
69	Was BRCA2 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6690690	Indicate whether mutation analysis of BRCA2 was performed. ***Note: If BRCA2 mutation analysis was performed, proceed to Question 70, otherwise, skip to Question 74.***
70	BRCA2 mutational analysis result	☐ No variant ☐ Benign variant ☐ Pathogenic variant (specify) ☐ Variant of uncertain significance (VUS) (specify)	6690691	Indicate the type of BRCA2 variant identified as a result of mutational analysis. ***Note: If a pathogenic variant or variant of uncertain significance was identified, proceed to Question 70a, otherwise, skip to Question 71.***
70a	Specify the BRCA2 variant	_____	6690693	Specify the pathogenic BRCA2 variant or BRCA2 variant of unknown significance identified as a result of mutational analysis.
71	Method used to identify BRCA2 mutation	☐ Next-generation targeted sequencing ☐ Whole exome sequencing ☐ Cancer hotspot panel (specify) ☐ Other (specify)	6003729	Indicate the method used in BRCA2 mutation analysis. ***Note: If a cancer hotspot panel was used, proceed to Question 72. If the method is not listed, proceed to Question 73, otherwise, skip to Question 74.***
72	Specify the panel sequencing test used to identify the BRCA2 mutation	_____	6690736	Specify the cancer hotspot panel used in BRCA2 mutation analysis.
73	Other method used to identify BRCA2 mutation	_____	6002204	If not included in the previous list, specify the method used in BRCA2 mutation analysis.
74	Was MLH1 IHC performed?	☐ Yes ☐ No ☐ Unknown	6062411	Indicate whether MLH1 expression was assessed by immunohistochemistry (IHC). ***Note: If MLH1 IHC was performed, proceed to Question 75, otherwise, skip to Question 76.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
75	MLH1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063668	Indicate the status of MLH1 protein expression as determined by immunohistochemistry (IHC).
76	MLH1 promoter methylation status	☐ Absent ☐ Present ☐ Not assessed ☐ Indeterminate	6033150	Indicate the methylation status of the MLH1 promoter.
77	Was MSH2 IHC performed?	☐ Yes ☐ No ☐ Unknown	6062412	Indicate whether MSH2 expression was assessed by immunohistochemistry (IHC). ***Note: If MSH2 IHC was performed, proceed to Question 78, otherwise, skip to Question 79.***
78	MSH2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063669	Indicate the status of MSH2 protein expression as determined by immunohistochemistry (IHC).
79	Was PMS2 IHC performed?	☐ Yes ☐ No ☐ Unknown	6062413	Indicate whether PMS2 expression was assessed by immunohistochemistry (IHC). ***Note: If PMS2 IHC was performed, proceed to Question 80, otherwise, skip to Question 81.***
80	PMS2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063670	Indicate the status of PMS2 protein expression as determined by immunohistochemistry (IHC).
81	Was MSH6 IHC performed?	☐ Yes ☐ No ☐ Unknown	6062414	Indicate whether MSH6 expression was assessed by immunohistochemistry (IHC). ***Note: If MSH6 IHC was performed, proceed to Question 82, otherwise, skip to Question 83.***
82	MSH6 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063671	Indicate the status of MSH6 protein expression as determined by immunohistochemistry (IHC).
83	Was p53 IHC performed?	☐ Yes ☐ No ☐ Unknown	6690705	Indicate whether p53 expression was assessed by immunohistochemistry (IHC). ***Note: If p53 IHC was performed, proceed to Question 84, otherwise, skip to Question 85.***
84	p53 expression by IHC	☐ Normal ☐ Abnormal strong diffuse overexpression (>90%) ☐ Abnormal null expression (complete loss of expression) ☐ Cannot be determined	6690719	Indicate the status of p53 protein expression as determined by immunohistochemistry (IHC).
85	Was ER IHC performed?	☐ Yes ☐ No ☐ Unknown	6062416	Indicate whether estrogen receptor (ER) expression was assessed by immunohistochemistry (IHC). ***Note: If ER IHC was performed, proceed to Question 86, otherwise, skip to Question 87.***
86	ER expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6690720	Indicate the status of estrogen receptor (ER) protein expression as determined by immunohistochemistry (IHC).
87	Was PR IHC performed?	☐ Yes ☐ No ☐ Unknown	6062504	Indicate whether progesterone receptor (PR) expression was assessed by immunohistochemistry (IHC). ***Note: If PR IHC was performed, proceed to Question 88, otherwise, skip to Question 89.***
88	PR expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063673	Indicate the status of progesterone receptor (PR) protein expression as determined by immunohistochemistry (IHC).
89	Was PAX-8 IHC performed?	☐ Yes ☐ No ☐ Unknown	6690706	Indicate whether PAX-8 expression was assessed by immunohistochemistry (IHC). ***Note: If PAX-8 IHC was performed, proceed to Question 90, otherwise, skip to Question 91.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
90	PAX-8 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6690721	Indicate the status of PAX-8 protein expression as determined by immunohistochemistry (IHC).
91	Was WT-1 IHC performed?	☐ Yes ☐ No ☐ Unknown	6690712	Indicate whether WT-1 expression was assessed by immunohistochemistry (IHC). ***Note: If WT-1 IHC was performed, proceed to Question 92, otherwise, skip to Question 93.***
92	WT-1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6690723	Indicate the status of WT-1 protein expression as determined by immunohistochemistry (IHC).
93	Was p16 IHC performed?	☐ Yes ☐ No ☐ Unknown	6690713	Indicate whether p16 expression was assessed by immunohistochemistry (IHC). ***Note: If p16 IHC was performed, proceed to Question 94, otherwise, skip to Question 95.***
94	p16 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6690724	Indicate the status of p16 protein expression as determined by immunohistochemistry (IHC).
95	Was HNF-1 IHC performed?	☐ Yes ☐ No ☐ Unknown	6690714	Indicate whether HNF-1 expression was assessed by immunohistochemistry (IHC). ***Note: If HNF-1 IHC was performed, proceed to Question 96, otherwise, skip to Question 97.***
96	HNF-1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6690731	Indicate the status of HNF-1 protein expression as determined by immunohistochemistry (IHC).
97	Was CDX-2 IHC performed?	☐ Yes ☐ No ☐ Unknown	6690715	Indicate whether CDX-2 expression was assessed by immunohistochemistry (IHC). ***Note: If CDX-2 IHC was performed, proceed to Question 98, otherwise, skip to Question 99.***
98	CDX-2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6690732	Indicate the status of CDX-2 protein expression as determined by immunohistochemistry (IHC).
99	Was CK-7 IHC performed?	☐ Yes ☐ No ☐ Unknown	6690716	Indicate whether CK-7 expression was assessed by immunohistochemistry (IHC). ***Note: If CK-7 IHC was performed, proceed to Question 100, otherwise, skip to Question 101.***
100	CK-7 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6690733	Indicate the status of CK-7 protein expression as determined by immunohistochemistry (IHC).
101	Was CK-20 IHC performed?	☐ Yes ☐ No ☐ Unknown	6690717	Indicate whether CK-20 expression was assessed by immunohistochemistry (IHC). ***Note: If CK-20 IHC was performed, proceed to Question 102, otherwise, skip to Question 103.***
102	CK-20 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6690717	Indicate whether CK-20 expression was assessed by immunohistochemistry (IHC).
Primary Tumor Sample Information				
103	Are you submitting a primary tumor tissue sample for this case?	☐ Yes ☐ No		***If yes, proceed to Question 104.*** ***If no and submitting a metastatic/recurrent tumor sample, proceed to Question 132.***
104	Primary tumor biospecimen ordinal	_____	6584265	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number should be "1".***
105	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
106	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
107	Sample represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this primary tumor specimen represent the PRIMARY DIAGNOSIS for this Case ID3? ***Note: If no, continue to Question 108, otherwise, skip to Question 109.***
108	Specify the ICD-10 code	_____	3226287	Provide the ICD-10 code for the primary tumor used to generate the model submitted to HCMI.
109	Tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the tumor tissue sample collected for molecular characterization.
110	Anatomic site of tumor from which Model was Derived	☐ Right ovary ☐ Left ovary ☐ Right fallopian tube ☐ Left fallopian tube ☐ Right tubo-ovarian ☐ Left tubo-ovarian ☐ Other (specify)	6033148	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI. ***Note: If the tissue or organ of origin is not listed, proceed to Question 110a, otherwise, skip to Question 111.***
110a	Other anatomic site from which the tumor was obtained	_____	5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.
111	Method of cancer sample procurement	☐ Total hysterectomy and bilateral salpingo-oophorectomy ☐ Radical hysterectomy ☐ Simple hysterectomy ☐ Supracervical hysterectomy ☐ Bilateral salpingo-oophorectomy ☐ Right salpingo-oophorectomy ☐ Left salpingo-oophorectomy ☐ Salpingo-oophorectomy, side not specified ☐ Bilateral salpingectomy ☐ Right salpingectomy ☐ Left salpingectomy ☐ Salpingectomy, side not specified ☐ Omentectomy ☐ Peritoneal biopsies ☐ Peritoneal tumor debulking ☐ Peritoneal washing ☐ Morcellated cystectomy ☐ Oophorectomy ☐ Ascites drainage ☐ Pleurocentesis (pleural fluid) ☐ Other (specify)	3103514	Provide the procedure performed to obtain the primary tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 111a, otherwise, skip to Question 112.***
111a	Specify the other method of tumor sample procurement	_____	2006730	Specify the procedure performed to obtain the primary tumor tissue, if not included in the previous list.
112	Number of days from index date to date of tumor sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the tumor tissue submitted for HCMI.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
113	Tumor tissue type	☐ Primary ☐ Additional Primary ☐ NOS	3288124	Provide the primary tumor tissue type for this sample.
Primary Tumor Model Information				
114	Primary model biospecimen ordinal	_____	6594596	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number is expected to be "1".***
115	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
116	BPC submitter ID (if available)		6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
117	Model represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this MODEL represent the PRIMARY DIAGNOSIS for this Case ID3?
118	Model's primary tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the PRIMARY TUMOR TISSUE from which this model is derived.
119	Model's primary tumor biospecimen ordinal	_____	6584265	Enter the biospecimen ordinal of the PRIMARY TUMOR TISSUE from which this model is derived.
Treatment Information				
120	History of neoadjuvant treatment	☐ No ☐ Yes; radiation prior to resection ☐ Yes; pharmaceutical treatment prior to resection ☐ Yes; both radiation and pharmaceutical treatment prior to resection ☐ Unknown	3382737	Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment. ***Note: Radiation therapy is addressed in Questions 130-131. Pharmaceutical therapy is addressed in Questions 121-129.***
121	Neoadjuvant chemotherapy type	☐ Cytotoxic chemotherapy ☐ Hormonal ☐ Immunotherapy (cellular and immune checkpoint) ☐ Targeted therapy (small molecule inhibitors and targeted antibodies) ☐ Not applicable	5832928	Select all neoadjuvant chemotherapy types that were administered to the patient. ***Note: Cytotoxic chemotherapy is addressed in Questions 122-123. Hormone therapy is addressed in Questions 124-125. Immunotherapy is addressed in Questions 126-127. Targeted therapy is addressed in Questions 128-129.***
122	Neoadjuvant chemotherapeutic regimen	☐ Albumin-bound paclitaxel ☐ Altretamine ☐ Capecitabine ☐ Carboplatin ☐ Cisplatin ☐ Cyclophosphamide ☐ Docetaxel ☐ Etoposide ☐ Gemcitabine ☐ Ifosfamide ☐ Irinotecan ☐ Liposomal doxorubicin ☐ Melphalan ☐ Paclitaxel ☐ Pemetrexed ☐ Topotecan ☐ Vinorelbine ☐ Other (specify) ☐ Chemotherapy not given	2853313	Select all chemotherapeutics used for neoadjuvant therapy. ***Note: If neoadjuvant chemotherapy was not administered, skip to Question 124. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 122a, otherwise, skip to Question 123.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
122a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapies administered.
123	Days to neoadjuvant chemotherapy treatment from index date	_____	5102411	Provide the number of days from index date to the date of treatment with neoadjuvant chemotherapy.
124	Hormone therapy	☐ Anastrozole ☐ Exemestane ☐ Goserelin ☐ Letrozole ☐ Leuprolide ☐ Tamoxifen ☐ Other (specify)	2582817	Select the hormone therapy administered to the patient. ***Note: If hormone therapy was not administered, skip to Question 126. If the hormone therapy is not listed, proceed to Question 124a, otherwise, skip to Question 125.***
124a	Other hormone therapy	_____	2405358	If the hormone therapy is not included in the provided list, specify hormone therapy.
125	Days to hormone therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with hormone therapy.
126	Immunotherapy	☐ Pembrolizumab ☐ Other (specify)	6690669	Select the immunotherapy administered to the patient. ***Note: If immunotherapy was not administered, skip to Question 128. If the immunotherapy is not listed, proceed to Question 126a, otherwise, skip to Question 127.***
126a	Other immunotherapy name	_____	2185614	If not provided in the previous list, specify the name of the immunotherapy administered to the patient.
127	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
128	Targeted Therapy	☐ Bevacizumab ☐ Niraparib ☐ Olaparib ☐ Rucaparib ☐ Other (specify)	6690668	Select the targeted molecular therapy administered to the patient. ***Note: If targeted therapy was not given, proceed to Question 130. If the targeted therapy is not listed, proceed to Question 128a, otherwise, skip to Question 129.***
128a	Specify targeted therapy	_____	4308476	Provide the name of the targeted therapy administered to the patient.
129	Days to targeted therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with targeted therapy.
130	Radiation therapy administered type	☐ 2D conventional ☐ 3D conformal ☐ Brachytherapy HDR ☐ Brachytherapy LDR ☐ IMRT ☐ Proton Beam ☐ Stereotactic Body RT ☐ Stereotactic Radiosurgery ☐ WBRT ☐ Other (specify) ☐ Unspecified ☐ Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. ***Note: If radiation therapy was not administered, proceed to Question 132. If the radiation therapy is not listed, proceed to Question 130a, otherwise, skip to Question 131.***
130a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
131	Days to radiation treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with radiation therapy.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Metastatic/Recurrent Tumor Biospecimen Information				
132	Are you submitting a metastatic/ recurrent tumor tissue sample?	☐ Yes ☐ No		Indicate whether a metastatic/recurrent tumor biospecimen was collected for this ID3 case. ***Note: If yes, proceed to Question 133. If submitting an OTHER tissue sample, proceed to Question 205. For multiple metastatic/recurrent tissues collected for model generation, Questions 132-195 can be repeated, as needed.***
133	Metastatic/ recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1", the second should be number "2", etc.***
134	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
135	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
136	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
137	Number of days from index date to date of diagnosis of metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic/recurrent disease.
138	Method of metastatic/ recurrent cancer sample procurement	☐ Total hysterectomy and bilateral salpingo-oophorectomy ☐ Radical hysterectomy ☐ Simple hysterectomy ☐ Supracervical hysterectomy ☐ Bilateral salpingo-oophorectomy ☐ Right salpingo-oophorectomy ☐ Left salpingo-oophorectomy ☐ Salpingo-oophorectomy, side not specified ☐ Bilateral salpingectomy ☐ Right salpingectomy ☐ Left salpingectomy ☐ Salpingectomy, side not specified ☐ Omentectomy ☐ Peritoneal biopsies ☐ Peritoneal tumor debulking ☐ Peritoneal washing ☐ Morcellated cystectomy ☐ Oophorectomy ☐ Ascites drainage ☐ Pleurocentesis (pleural fluid) ☐ Other (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 138a, otherwise, skip to Question 139.***
138a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
139	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
140	Metastatic/ recurrent site	☐ Liver ☐ Lung ☐ Peritoneum ☐ Omentum ☐ Pleura ☐ Lymph nodes ☐ Right ovary ☐ Left ovary ☐ Right fallopian tube ☐ Left fallopian tube ☐ Right tubo-ovarian ☐ Left tubo-ovarian ☐ Ascites ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 140a, otherwise, skip to Question 141.***
140a	Other metastatic/ recurrent site	_____	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
141	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
142	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
143	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
144	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
145	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
146	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
147	Is the patient still receiving treatment?	_____	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
148	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
149	Tumor size, largest dimension	_____ cm	64215	Provide the largest dimension of the primary tumor in cm, regardless of anatomical plane.
150	Other tissue/organ involvement (select all that apply)	☐ Right ovary ☐ Left ovary ☐ Ovary (side not specified) ☐ Right fallopian tube ☐ Left fallopian tube ☐ Fallopain tube (side not specified) ☐ Uterus ☐ Cervix ☐ Pelvic peritoneum ☐ Abdominal peritoneum ☐ Omentum ☐ Not applicable ☐ Not identified ☐ Other (specify)	2793699	Select all sites of other tissue/organ involvement. This does not include the primary tumor site. ***Note: If the other tissue/organ is not listed, proceed to Question 150a, otherwise, skip to Question 151.***
150a	Specify other tissue/organ involvement	_____	6690678	If not included in the previous list, specify the other site of other tissue/organ involvement. This does not include the primary tumor site.
151	Peritoneal/Ascitic fluid	☐ Not submitted/unknown ☐ Negative for malignancy (normal/benign) ☐ Atypical and/or suspicious ☐ Malignant (positive for malignancy) ☐ Unsatisfactory/nondiagnostic	6690681	Indicate the outcome of cytological analysis for peritoneal/ascitic fluid.
152	Number of positive lymph nodes	_____	89	Provide the number of lymph nodes with disease involvement.
153	Number of lymph nodes examined	_____	3	Provide the total number of lymph nodes tested for the presence of cancer cells.
154	Additional pathologic findings	☐ None identified ☐ Serous tubal intraepithelial carcinoma (STIC) ☐ Endometriosis ☐ Endosalpingiosis ☐ Other (specify)	6690682	Indicate additional pathologic findings present in the patient. ***Note: If the additional pathologic finding is not listed, proceed to Question 154a, otherwise, skip to Question 155.***
154a	Specify additional pathologic findings	_____	6690683	If not included in the previous list, specify any additional pathologic findings.
155	CA-125 during follow-up/ at the time of recurrence	_____	3008730	Provide the numeric value of CA-125 at the time of follow-up or initial disease recurrence.
Metastatic/Recurrent Tumor Sample: Clinical Molecular Analyses				
156	Was BRCA1 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6690686	Indicate whether mutation analysis of BRCA1 was performed.
157	BRCA1 mutational analysis result	☐ No variant ☐ Benign variant ☐ Pathogenic variant (specify) ☐ Variant of uncertain significance (VUS) (specify)	6690687	Indicate the type of BRCA1 variant identified as a result of mutational analysis. ***Note: If a pathogenic variant or variant of uncertain significance was identified, proceed to Question 157a, otherwise, skip to Question 158.***
157a	Specify BRCA1 variant	_____	6690688	Specify the pathogenic BRCA1 variant or BRCA1 variant of unknown significance identified as a result of mutational analysis.
158	Method used to identify BRCA1 mutation	☐ Next-generation targeted sequencing ☐ Whole exome sequencing ☐ Cancer hotspot panel (specify) ☐ Other (specify)	6003729	Indicate the method used in BRCA1 mutation analysis. ***Note: If a cancer hotspot panel was used, proceed to Question 159. If the method is not listed, proceed to Question 160, otherwise, skip to Question 161.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
159	Specify the panel sequencing test used to identify the BRCA1 mutation	_____	6690689	Specify the cancer hotspot panel used in BRCA1 mutation analysis.
160	Other method used to identify BRCA1 mutation	_____	6002204	If not included in the previous list, specify the method used in BRCA1 mutation analysis.
161	Was BRCA2 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6690690	Indicate whether mutation analysis of BRCA2 was performed.
162	BRCA2 mutational analysis result	☐ No variant ☐ Benign variant ☐ Pathogenic variant (specify) ☐ Variant of uncertain significance (VUS) (specify)	6690691	Indicate the type of BRCA2 variant identified as a result of mutational analysis. ***Note: If a pathogenic variant or variant of uncertain significance was identified, proceed to Question 162a, otherwise, skip to Question 163.***
162a	Specify BRCA2 variant	_____	6690693	Specify the pathogenic BRCA2 variant or BRCA2 variant of unknown significance identified as a result of mutational analysis.
163	Method used to identify BRCA2 mutation	☐ Next-generation targeted sequencing ☐ Whole exome sequencing ☐ Cancer hotspot panel (specify) ☐ Other (specify)	6003729	Indicate the method used in BRCA2 mutation analysis. ***Note: If a cancer hotspot panel was used, proceed to Question 164. If the method is not listed, proceed to Question 165, otherwise, skip to Question 166.***
164	Specify the panel sequencing test used to identify the BRCA2 mutation	_____	6690736	Specify the cancer hotspot panel used in BRCA2 mutation analysis.
165	Other method used to identify BRCA2 mutation	_____	6002204	If not included in the previous list, specify the method used in BRCA2 mutation analysis.
166	Was MLH1 IHC performed?	☐ Yes ☐ No ☐ Unknown	6062411	Indicate whether MLH1 expression was assessed by immunohistochemistry (IHC). ***Note: If MLH1 IHC was performed, proceed to Question 167, otherwise, skip to Question 168.***
167	MLH1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063668	Indicate the status of MLH1 protein expression as determined by immunohistochemistry (IHC).
168	MLH1 promoter methylation status	☐ Absent ☐ Present ☐ Not assessed ☐ Indeterminate	6033150	Indicate the methylation status of the MLH1 promoter.
169	Was MSH2 IHC performed?	☐ Yes ☐ No ☐ Unknown	6062412	Indicate whether MSH2 expression was assessed by immunohistochemistry (IHC). ***Note: If MSH2 IHC was performed, proceed to Question 170, otherwise, skip to Question 171.***
170	MSH2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063669	Indicate the status of MSH2 protein expression as determined by immunohistochemistry (IHC).
171	Was PMS2 IHC performed?	☐ Yes ☐ No ☐ Unknown	6062413	Indicate whether PMS2 expression was assessed by immunohistochemistry (IHC). ***Note: If PSM2 IHC was performed, proceed to Question 172, otherwise, skip to Question 173.***
172	PMS2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063670	Indicate the status of PMS2 protein expression as determined by immunohistochemistry (IHC).
173	Was MSH6 IHC performed?	☐ Yes ☐ No ☐ Unknown	6062414	Indicate whether MSH6 expression was assessed by immunohistochemistry (IHC). ***Note: If MSH6 IHC was performed, proceed to Question 174, otherwise, skip to Question 175.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
174	MSH6 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063671	Indicate the status of MSH6 protein expression as determined by immunohistochemistry (IHC).
175	Was p53 IHC performed?	☐ Yes ☐ No ☐ Unknown	6690705	Indicate whether p53 expression was assessed by immunohistochemistry (IHC). ***Note: If p53 IHC was performed, proceed to Question 176, otherwise, skip to Question 177.***
176	p53 expression by IHC	☐ Normal ☐ Abnormal strong diffuse overexpression (>90%) ☐ Abnormal null expression (complete loss of expression) ☐ Cannot be determined	6690719	Indicate the status of p53 protein expression as determined by immunohistochemistry (IHC).
177	Was ER IHC performed?	☐ Yes ☐ No ☐ Unknown	6062416	Indicate whether estrogen receptor (ER) expression was assessed by immunohistochemistry (IHC). ***Note: If ER IHC was performed, proceed to Question 178, otherwise, skip to Question 179.***
178	ER expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6690720	Indicate the status of estrogen receptor (ER) protein expression as determined by immunohistochemistry (IHC).
179	Was PR IHC performed?	☐ Yes ☐ No ☐ Unknown	6062504	Indicate whether progesterone receptor (PR) expression was assessed by immunohistochemistry (IHC). ***Note: If PR IHC was performed, proceed to Question 180, otherwise, skip to Question 181.***
180	PR expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063673	Indicate the status of progesterone receptor (PR) protein expression as determined by immunohistochemistry (IHC).
181	Was PAX-8 IHC performed?	☐ Yes ☐ No ☐ Unknown	6690706	Indicate whether PAX-8 expression was assessed by immunohistochemistry (IHC). ***Note: If PAX-8 IHC was performed, proceed to Question 182, otherwise, skip to Question 183.***
182	PAX-8 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6690721	Indicate the status of PAX-8 protein expression as determined by immunohistochemistry (IHC).
183	Was WT-1 IHC performed?	☐ Yes ☐ No ☐ Unknown	6690712	Indicate whether WT-1 expression was assessed by immunohistochemistry (IHC). ***Note: If WT-1 IHC was performed, proceed to Question 184, otherwise, skip to Question 185.***
184	WT-1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6690723	Indicate the status of WT-1 protein expression as determined by immunohistochemistry (IHC).
185	Was p16 IHC performed?	☐ Yes ☐ No ☐ Unknown	6690713	Indicate whether p16 expression was assessed by immunohistochemistry (IHC). ***Note: If p16 IHC was performed, proceed to Question 186, otherwise, skip to Question 187***
186	p16 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6690724	Indicate the status of p16 protein expression as determined by immunohistochemistry (IHC).
187	Was HNF-1 IHC performed?	☐ Yes ☐ No ☐ Unknown	6690714	Indicate whether HNF-1 expression was assessed by immunohistochemistry (IHC). ***Note: If HNF-1 IHC was performed, proceed to Question 188, otherwise, skip to Question 189.***
188	HNF-1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6690731	Indicate the status of HNF-1 protein expression as determined by immunohistochemistry (IHC).



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
189	Was CDX-2 IHC performed?	☐ Yes ☐ No ☐ Unknown	6690715	Indicate whether CDX-2 expression was assessed by immunohistochemistry (IHC). ***Note: If CDX-2 IHC was performed, proceed to Question 190, otherwise, skip to Question 191.***
190	CDX-2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6690732	Indicate the status of CDX-2 protein expression as determined by immunohistochemistry (IHC).
191	Was CK-7 IHC performed?	☐ Yes ☐ No ☐ Unknown	6690716	Indicate whether CK-7 expression was assessed by immunohistochemistry (IHC). ***Note: If CK-7 IHC was performed, proceed to Question 192, otherwise, skip to Question 193.***
192	CK-7 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6690733	Indicate the status of CK-7 protein expression as determined by immunohistochemistry (IHC).
193	Was CK-20 IHC performed?	☐ Yes ☐ No ☐ Unknown	6690717	Indicate whether CK-20 expression was assessed by immunohistochemistry (IHC). ***Note: If CK-20 IHC was performed, proceed to Question 194, otherwise, skip to Question 195.***
194	CK-20 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6690735	Indicate the status of CK-20 protein expression as determined by immunohistochemistry (IHC).
Metastatic/Recurrent Tumor Model Information				
195	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
196	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
197	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
198	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
199	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Additional Metastatic/Recurrent Biospecimen Tumor Model Information (if applicable)				
200	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
201	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
202	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
203	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
204	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Other Biospecimen Information				
205	Are you submitting an OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an OTHER tissue sample (e.g. pre-malignant, non-malignant, or dysplastic tissue, etc.) was collected for HCMI for this case. ***Note: If yes, proceed to Question 206.***
206	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
207	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
208	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
209	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
210	Other method of cancer sample procurement	☐ Total hysterectomy and bilateral salpingo-oophorectomy ☐ Radical hysterectomy ☐ Simple hysterectomy ☐ Supracervical hysterectomy ☐ Bilateral salpingo-oophorectomy ☐ Right salpingo-oophorectomy ☐ Left salpingo-oophorectomy ☐ Salpingo-oophorectomy, side not specified ☐ Bilateral salpingectomy ☐ Right salpingectomy ☐ Left salpingectomy ☐ Salpingectomy, side not specified ☐ Omentectomy ☐ Peritoneal biopsies ☐ Peritoneal tumor debulking ☐ Peritoneal washing ☐ Morcellated cystectomy ☐ Oophorectomy ☐ Ascites drainage ☐ Pleurocentesis (pleural fluid) ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 210a, otherwise, skip to Question 211.***
210a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
211	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
212	Tissue type	☐ Pre-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 212a, otherwise, skip to Question 213.***
212a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
213	Anatomic site of OTHER tissue	☐ Liver ☐ Lung ☐ Peritoneum ☐ Omentum ☐ Pleura ☐ Lymph nodes ☐ Right ovary ☐ Left ovary ☐ Right fallopian tube ☐ Left fallopian tube ☐ Right tubo-ovarian ☐ Left tubo-ovarian ☐ Ascites ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 213a, otherwise, skip to Question 214.***
213a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.
214	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
215	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Additional OTHER biospecimen Information (if applicable)				
216	Are you submitting an additional OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an additional OTHER tissue sample (pre-malignant, non-malignant, or dysplastic tissue, etc.) is being submitted for HCMI for this case. ***Note: If yes, proceed to Question 217. If no, proceed to Question 227.***
217	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
218	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
219	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
220	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.



Enrollment: Ovarian

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
221	Other method of cancer sample procurement	☐ Total hysterectomy and bilateral salpingo-oophorectomy ☐ Radical hysterectomy ☐ Simple hysterectomy ☐ Supracervical hysterectomy ☐ Bilateral salpingo-oophorectomy ☐ Right salpingo-oophorectomy ☐ Left salpingo-oophorectomy ☐ Salpingo-oophorectomy, side not specified ☐ Bilateral salpingectomy ☐ Right salpingectomy ☐ Left salpingectomy ☐ Salpingectomy, side not specified ☐ Omentectomy ☐ Peritoneal biopsies ☐ Peritoneal tumor debulking ☐ Peritoneal washing ☐ Morcellated cystectomy ☐ Oophorectomy ☐ Ascites drainage ☐ Pleurocentesis (pleural fluid) ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 221a, otherwise, skip to Question 222.***
221a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
222	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
223	Tissue type	☐ Pre-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 223a, otherwise, skip to Question 224.***
223a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
224	Anatomic site of OTHER tissue	☐ Liver ☐ Lung ☐ Peritoneum ☐ Omentum ☐ Pleura ☐ Lymph nodes ☐ Right ovary ☐ Left ovary ☐ Right fallopian tube ☐ Left fallopian tube ☐ Right tubo-ovarian ☐ Left tubo-ovarian ☐ Ascites ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 224a, otherwise, skip to Question 225.***
224a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.
225	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.



Enrollment: Ovarian

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
226	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Other Tissue Model Information				
227	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
228	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
229	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
230	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
231	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.
Additional Other Tissue Model Information (if applicable)				
232	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
233	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
234	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
235	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
236	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.



Enrollment: Pancreas

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Form Notes: An Enrollment Form should be completed for each HCMI case upon qualification notice from Leidos. All information provided on this form should include activity from the Date of Initial Pathologic Diagnosis to the most recent Date of Last Contact with the patient.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	☐ Initial pathologic diagnosis ☐ Sample procurement ☐ First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.
Patient Information				
4	Gender	☐ Male ☐ Female ☐ Unspecified	2200604	Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
5	Height	_____	649	Provide the patient's height, in centimeters.
6	Weight	_____	651	Provide the patient's weight, in kilograms.
7	Body mass index (BMI)	_____	2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
8	Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown ☐ Not reported	2192199	Provide the patient's race using the defined categories. **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 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. **Black or African American:** A person having origins in any of the black racial groups of Africa. **Native Hawaiian or other Pacific Islander:** A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island. **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
9	Ethnicity	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Not reported	2192217	Provide the patient's ethnicity using the defined categories. **Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. **Not Hispanic or Latino:** A person not meeting the definition of Hispanic or Latino.



Enrollment: Pancreas

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
10	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.
11	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. ***Note: If the patient's age is greater than 32,872 days (90 years), please enter 32,872.***
12	Year of birth	_____	2896954	Provide the year of the patient's birth. If the patient was born prior to 1928, insert the date 1928.
13	Family history of cancer	☐ Same ☐ Different ☐ None ☐ Unknown	5832923	Has a first-degree relative of the patient been diagnosed with a cancer of the same or a different type?
14	Smoking history	☐ Lifelong non-smoker (<100 cigarettes smoked in a lifetime) ☐ Current smoker (includes daily and non-daily smokers) ☐ Current reformed smoker (duration not specified) ☐ Current reformed smoker for >15 years ☐ Current reformed smoker for ≤15 years	2181650	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories.
15	Metastasis at diagnosis assessment status	☐ Metastatic ☐ Non-metastatic (confirmed) ☐ Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor. ***Note: If metastatic at diagnosis, proceed to Question 16, otherwise, skip to Question 17.***
16	Metastatic site(s) at diagnosis	☐ Liver ☐ Lung ☐ Peritoneum ☐ Other (specify)	3029815	Indicate the site(s) of metastasis at the time of diagnosis of the primary tumor. ***Note: If the anatomic site of tumor tissue is not listed, proceed to Question 16a, otherwise, skip to Question 17.***
16a	Specify metastatic site(s)	_____	3128033	If the site of metastasis is not included on the provided list, specify the site of metastasis.
17	Alcohol exposure intensity	☐ Drinker ☐ Heavy drinker ☐ Lifetime non-drinker ☐ Non-drinker ☐ Occasional drinker ☐ Not evaluated	3457767	Select the patient's current level of alcohol use as self-reported by the patient.
18	Amount of alcohol consumption per week	_____	3114013	Provide the average number of days each week that the patient consumes an alcoholic beverage.
19	History of diabetes	☐ Yes ☐ No ☐ Unknown	3197322	Indicate whether the patient has a diagnosis of diabetes. ***Note: If the patient does not have a history of diabetes, skip to Question 22.***
20	Number of days from the index date to the date of diabetes onset	_____	3457768	Provide the number of days from the index date to the date the patient was diagnosed with diabetes.
21	Diabetes treatment	☐ Injected insulin ☐ Biguanide ☐ Sulfonylurea ☐ Thiazolidinedione ☐ Alpha-glucosidase inhibitor ☐ Other (specify)	3587247	Select all diabetes mellitus treatments given to the patient. ***Note: If the diabetes treatment is not listed, proceed to Question 21a, otherwise, skip to Question 22.***



Enrollment: Pancreas

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
21a	Other diabetes treatment	_____	3587240	If the patient's diabetes treatment is not included on the previous list, provide the name of the other diabetes treatment.
22	Prior clinical history, if known	☐ IPMN ☐ Chronic pancreatitis ☐ Neuroendocrine tumor ☐ Adenocarcinoma ☐ Not applicable ☐ Unknown	5983086	Provide the patient's clinical history that may increase risk of pancreatic cancer.
23	Basis of diagnosis of prior clinical history	☐ Histologic ☐ Pathologic ☐ Radiologic ☐ Not applicable	5946730	Select the method used to determine the diagnosis of prior clinical history.
24	History of clinical chronic pancreatitis	☐ Yes ☐ No	3457760	Indicate whether or not the patient has a history of clinical chronic pancreatitis. ***Note: If the patient does not have a history of chronic pancreatitis, skip to Question 26.***
25	Year of chronic pancreatitis diagnosis	_____	3457763	Provide the year that the patient was diagnosed with clinical chronic pancreatitis.
Biospecimen Information				
26	Tissue sample type(s) collected for HCMI for this case	☐ Normal tissue ☐ Primary tumor ☐ Metastatic ☐ Recurrent ☐ Other tissue	2006911	Please select all the tissue sample types submitted for HCMI with this case.
27	Number of NORMAL tissues biospecimens collected for HCMI for this case	_____	6584256	Please provide the number of normal tissue specimens obtained for HCMI for this case. ***Note: This number is expected to be 1.***
28	Number of PRIMARY cancer tissue biospecimens collected for HCMI model development for this case	_____	6584257	Please provide the number of primary tumor specimens obtained for HCMI for this case. ***Note: A single primary tumor biospecimen obtained that is portioned for both sequencing and model generation counts as 1 single primary tumor specimen. This number is expected to be 1.***
29	Number of METASTATIC/RECURRENT cancer tissue biospecimens collected for HCMI model development for this case	_____	6584258	Please provide the number of metastatic and/or recurrent cancer biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
30	Number of OTHER tissue biospecimens collected for HCMI model development for this case	_____	6584259	Please provide the number of pre-malignant, non-malignant, or dysplastic tissue biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***



Enrollment: Pancreas

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
31	Total number of tissue biospecimens collected for HCMI for this case	_____	6584271	Please provide the total number of tissue biospecimens collected for HCMI for this case. ***Note: This number should be the sum of the normal, primary tumor, metastatic/ recurrent tumor, and other biospecimen counts above.***
Normal Control Information				
32	Normal tissue biospecimen ordinal	_____	6584264	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
33	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
34	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
35	Type of normal control	☐ Whole blood ☐ Buccal cells ☐ Buffy coat ☐ Lymphocytes ☐ Extracted DNA from blood ☐ Extracted DNA from saliva ☐ Extracted DNA from buccal cells ☐ Extracted DNA from normal tissue ☐ FFPE non-neoplastic tissue ☐ Non-neoplastic tissue	3081936	Indicate the type of normal control submitted for this case.
36	Anatomic site of normal tissue	☐ Duodenum ☐ Gastrointestinal ☐ Pancreas ☐ Skin ☐ Spleen ☐ Other (specify) ☐ Not applicable	4132152	If non-neoplastic tissue was submitted as the normal control, select the anatomic site of the normal tissue. ***Note: If the anatomic site of normal tissue is not listed, proceed to Question 36a, otherwise, skip to Question 37.***
36a	Other anatomic site of normal tissue	_____	3288189	If non-neoplastic tissue, adjacent tissue, or normal tissue from another anatomic site was submitted as the normal control, provide the anatomic site of the normal tissue.
37	Distance from tumor to normal control tissue (if not blood)	☐ Adjacent (< or = 2cm) ☐ Distal (>2cm) ☐ Unknown ☐ Not applicable	3088708	Indicate the distance from the site of normal tumor collection to the primary tumor. ***Note: If normal tissue was not submitted, select 'Not applicable'.***
38	Normal tissue sample preservation method	☐ Cryopreserved ☐ OCT ☐ FFPE ☐ Snap frozen ☐ Frozen	5432521	Provide the method used to preserve the normal tissue sample collected for molecular characterization.
Primary Tumor Biospecimen Information				
39	ICD-10 code for primary tumor	☐ C25.0 ☐ C25.7 ☐ C25.1 ☐ C25.8 ☐ C25.2 ☐ C25.9 ☐ C25.3 ☐ Other (specify) ☐ C25.4	3226287	Provide the ICD-10 code for the primary tumor as used to generate the ID3 for this subject. ***Note: If the ICD-10 code is not listed, proceed to 39a, otherwise, skip to Question 40.***



Enrollment: Pancreas

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
39a	Other ICD-10 code for primary tumor	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.
40	Tumor Morphology	☐ 8013/3 ☐ 8020/3 ☐ 8035/3 ☐ 8041/3 ☐ 8246/3 ☐ 8441/3 ☐ 8452/3 ☐ 8453/3 ☐ 8470/3 ☐ 8480/3 ☐ 8490/3 ☐ 8500/3 ☐ 8510/3 ☐ 8550/3 ☐ 8551/3 ☐ 8560/3 ☐ 8576/3 ☐ 8971/3 ☐ Other (specify)	3226275	Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor. ***Note: If the ICD-O-3 histology code of the primary tumor is not listed, proceed to Question 40a, otherwise, skip to Question 41.***
40a	Specify other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.
41	Tissue or organ of origin	☐ Pancreas ☐ Other (specify)	3427536	Using the patient's pathology/laboratory report, select the primary site of the disease. ***Note: If the primary site of the disease is not listed, proceed to Question 41a, otherwise skip to Question 42.***
41a	Other tissue or organ of origin	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	3427536	If the primary site of the disease is not included on the previous list, provide the primary site of the disease.



Enrollment: Pancreas

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
42	Histological Type	☐ Pancreatic cancer ☐ Other (specify)	3081932	Select the surgical pathology text description of the histological tumor type. ***Note: If the histological tumor type is not listed, proceed to Question 42a, otherwise, skip to Question 43.***
42a	Other histological type	_____	3294805	If the traditional surgical pathology text description of the histological tumor type is not included on the previous list, please specify the histological type.
43	Histological subtype	☐ Acinar cell carcinoma ☐ Acinar cell cystadenocarcinoma ☐ Adenocarcinoma ductal type ☐ Hepatoid carcinoma ☐ High-grade neuroendocrine carcinoma (large cell type) ☐ High-grade neuroendocrine carcinoma (small cell type) ☐ Inflammatory myofibroblastic tumor ☐ Intraductal papillary mucinous neoplasm (IPMN, main duct/mixed) ☐ Intraductal papillary mucinous neoplasm (IPMN, side duct) ☐ Invasive adenocarcinoma arising from IPMN ☐ Invasive carcinoma arising in MCN ☐ Medullary carcinoma ☐ Mixed acinar-ductal carcinomas ☐ Mixed acinar-neuroendocrine carcinoma ☐ Mixed ductal-neuroendocrine carcinoma ☐ Mucinous cystic neoplasms (MCN) ☐ Pancreas colloid (mucinous non-cystic) carcinoma ☐ Pancreatoblastoma ☐ Serous cystic adenoma (SCA) ☐ Signet ring cell carcinoma ☐ Solid pseudopapillary neoplasm ☐ Undifferentiated (anaplastic) carcinoma ☐ Undifferentiated carcinoma with osteoclast-like giant cells ☐ Unknown ☐ Other (specify)	3081934	Using the patient's pathology/laboratory report, select the histological subtype of the primary tumor. ***Note: If the histological subtype is not listed, proceed to Question 43a, otherwise, skip to Question 44.***
43a	Other histological subtype	_____	5946219	If the histological subtype for the primary tumor is not included in the provided list, specify the histological subtype.
44	Prior malignancy (of the same cancer type)	☐ Yes ☐ No ☐ Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
45	Prior malignancy (other cancer type)	☐ Yes ☐ No ☐ Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.
46	AJCC cancer staging edition	☐ 1st ☐ 4th ☐ 7th ☐ 2nd ☐ 5th ☐ 8th ☐ 3rd ☐ 6th	2722309	Select the AJCC staging handbook edition used to stage the patient's primary tumor.
47	AJCC clinical stage group	☐ Stage 0 ☐ Stage IIA ☐ Stage I ☐ Stage IIB ☐ Stage IA ☐ Stage III ☐ Stage IB ☐ Stage IV	3440332	Using the patient's pathology/laboratory report, select the clinical stage group of the primary tumor as defined by the American Joint Committee on Cancer (AJCC).



Enrollment: Pancreas

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
48	AJCC pathologic spread: Primary tumor (pT)	☐ T0 ☐ Tis ☐ T1 ☐ T1a ☐ T1b ☐ T1c ☐ T2 ☐ T3 ☐ T4 ☐ TX	3045435	Using the patient's pathology/laboratory report, select the code for the pathologic T (primary tumor) as defined by the American Joint Committee on Cancer (AJCC).
49	AJCC pathologic spread: Lymph nodes (pN)	☐ N0 ☐ N1 ☐ N2 ☐ NX	3203106	Using the patient's pathology/laboratory report, select the code for the pathologic N (nodal) as defined by the American Joint Committee on Cancer (AJCC).
50	AJCC pathologic spread: Distant metastases (pM)	☐ M0 ☐ M1 ☐ M1a ☐ M1b ☐ M1c	3045439	Using the patient's pathology/laboratory report, select the code for the pathologic M (metastasis) as defined by the American Joint Committee on Cancer (AJCC).
51	AJCC tumor stage (pathological)	☐ Stage 0 ☐ Stage I ☐ Stage 1A ☐ Stage 1B ☐ Stage IIA ☐ Stage IIB ☐ Stage III ☐ Stage IV	3065862	Using the patient's pathology/laboratory report, in conjunction with the patient's medical record, select the tumor stage as defined by the American Joint Committee on Cancer (AJCC).
52	Tumor grade	☐ G1-Well differentiated ☐ G2-Moderately differentiated ☐ G3-Poorly differentiated ☐ GX-Unknown	2785839	Using the patient's pathology/laboratory report, select the grade of the primary tumor.
53	Number of peripancreatic lymph nodes tested at surgery	_____	6050944	Provide the total number of peripancreatic lymph nodes tested for the presence of pancreatic cancer cells.
54	Number of positive peripancreatic lymph nodes	☐ 0 ☐ 1-3 ☐ ≥4 ☐ Unknown	5983082	Select the numeric range of the number of peripancreatic lymph nodes that tested positive for the presence of pancreatic cancer cells.
55	Has the CEA level of the patient been determined?	☐ Yes ☐ No	3107563	Indicate whether the Carcinoembryonic antigen (CEA) level of the patient has been determined. ***Note: If the patient's CEA level has not been determined, skip to Question 58.***
56	CEA level	_____	2752	Provide the patient's carcinoembryonic (CEA) level (ng/ml).
57	CEA level upper limit of normal value	_____	2002247	Provide the numeric laboratory value (ng/ml) representing the upper level of the normal range of values for carcinoembryonic antigen (CEA) in blood used to comparatively reference the patient's lab result.
58	Was tumor marker CA-19-9 test performed?	☐ Yes ☐ No ☐ Unknown	2891778	Indicate whether the patient's tumor marker CA-19-9 value was assessed. ***Note: If the CA-19-9 test was not performed, skip to Question 60.***
59	What was the CA-19-9 value?	_____	65302	Provide the patient's CA-19-9 level.
Primary Tumor Clinical Molecular Characterization				
60	Was KRAS mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6060079	Indicate whether KRAS mutation analysis was performed. ***Note: If not performed, skip to Question 61.***
61	Was a mutation in KRAS identified	☐ Yes ☐ No	6060081	Indicate whether a mutation in KRAS was identified through mutation analysis. ***Note: If mutation was not identified, skip to Question 63.***



Enrollment: Pancreas

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
62	If KRAS mutation identified, which one?	☐ G12A ☐ G12C ☐ G12D ☐ G12R ☐ G12S ☐ G12V ☐ G13D ☐ G13R ☐ G13C ☐ G13A ☐ G13V ☐ Q61L ☐ Q61H ☐ A146T ☐ Other (specify)	6060083	Indicate the specific KRAS mutation identified. ***Note: If the KRAS mutation is not listed, proceed to Question 62a, otherwise, skip to Question 63.***
62a	Other KRAS mutation(s)	_____	6101691	If the KRAS mutation identified is not provided in the previous list, specify the KRAS mutation.
63	Was TP53 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063448	Indicate whether TP53 mutation analysis was performed. ***Note: If not performed, skip to Question 65.***
64	If TP53 mutation identified, which one?	☐ R175H ☐ R213L ☐ Y220C ☐ C238Y ☐ G245D ☐ G245S ☐ R248Q ☐ R248W ☐ G266E ☐ G266V ☐ V272M ☐ R273C ☐ R273H ☐ R273L ☐ R282G ☐ R282W ☐ Other (specify)	6063731	Indicate the specific TP53 mutation identified. ***Note: If the TP53 mutation is not listed, proceed to Question 64a, otherwise, skip to Question 65***
64a	Other TP53 mutation(s)	_____	6101683	If the TP53 mutation identified is not provided in the previous list, specify the TP53 mutation.
65	Was CDKN2A mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063449	Indicate whether CDKN2A mutation analysis was performed. ***Note: If not performed, skip to Question 68.***
66	Was a mutation in CDKN2A identified?	☐ Yes ☐ No	6063534	Indicate whether a mutation in CDKN2A was identified through mutation analysis. ***Note: If mutation was not identified, skip to Question 68.***
67	If CDKN2A mutation identified, which one?	☐ A30V ☐ V51D ☐ V51I ☐ H83P ☐ H83Y ☐ D108H ☐ D108Y ☐ L130Q ☐ A147T ☐ A148T ☐ Other (specify)	6063732	Indicate the specific CDKN2A mutation identified. ***Note: If the CDKN2A mutation is not listed, proceed to Question 67a, otherwise, skip to Question 68.***
67a	Other CDKN2A mutation(s)	_____	6101684	If the CDKN2A mutation identified is not provided in the previous list, specify the CDKN2A mutation.
68	Was GNAS mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063450	Indicate whether GNAS mutation analysis was performed. ***Note: If not performed, skip to Question 71.***
69	Was a mutation in GNAS identified?	☐ Yes ☐ No	5983161	Indicate whether a mutation in GNAS was identified through mutation analysis. ***Note: If mutation was not identified, skip to Question 71.***
70	If GNAS mutation identified, which one?	☐ Q125R ☐ R160C ☐ R201C ☐ R201H ☐ R201S ☐ Q227E ☐ Q227L ☐ Q227P ☐ Q227R ☐ Other (specify)	6063733	Indicate the specific GNAS mutation identified. ***Note: If the GNAS mutation is not listed, proceed to Question 70a, otherwise, skip to Question 71.***
70a	Other GNAS mutation(s)	☐ _____	6101685	If the GNAS mutation identified is not provided in the previous list, specify the GNAS mutation.
71	Was RNF43 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063451	Indicate whether RNF43 mutation analysis was performed. ***Note: If not performed, skip to Question 72.***
72	Was a mutation in RNF43 identified?	☐ Yes ☐ No	5983286	Indicate whether a mutation in RNF43 was identified through mutation analysis. ***Note: If mutation was not identified, skip to Question 74.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
73	If RNF43 mutation identified, which one?	☐ R127P ☐ A169T ☐ D140E ☐ E318D ☐ P154L ☐ Other (specify)	6063734	Indicate the specific RNF43 mutation identified. ***Note: If the RNF43 mutation is not listed, proceed to Question 73a, otherwise, skip to Question 74.***
73a	Other RNF43 mutation(s)	_____	6101686	If the RNF43 mutation identified is not provided in the previous list, specify the RNF43 mutation.
74	Was SMAD4 IHC performed?	☐ Yes ☐ No ☐ Unknown	6063646	Indicate whether SMAD4 protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If not performed, skip to Question 76.***
75	SMAD4 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063676	Indicate the status of SMAD4 protein expression as determined by immunohistochemistry (IHC).
Primary Tumor Sample Information				
76	Are you submitting a primary tumor tissue sample for this case?	☐ Yes ☐ No		***If yes, proceed to question 77, otherwise, skip to Question 93.***
77	Primary tumor biospecimen ordinal	_____	6584265	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number should be "1".***
78	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
79	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
80	Sample represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this primary tumor specimen represent the PRIMARY DIAGNOSIS for this Case ID3? ***Note: If no, continue to Question 81, otherwise, skip to Question 82.***
81	Specify the ICD-10 code	_____	3226287	Provide the ICD-10 code for the primary tumor used to generate the model submitted to HCMI.
82	Tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the tumor tissue sample collected for molecular characterization.
83	Anatomic site of tumor from which model was derived	☐ Pancreatic head ☐ Lung ☐ Pancreatic body ☐ Lymph node ☐ Pancreatic tail ☐ Peritoneum ☐ Liver ☐ Other (specify)	6033148	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI. ***Note: If the tissue or organ of origin is not listed, proceed to Question 83a. Otherwise, skip to Question 84.***
83a	Other anatomic site from which the tumor was obtained	_____	5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.
84	Method of cancer sample procurement	☐ Core needle biopsy ☐ Distal partial pancreatectomy ☐ Fine needle aspiration biopsy ☐ Paracentesis ☐ Whipple procedure ☐ Other method (specify)	3103514	Provide the procedure performed to obtain the primary tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 84a, otherwise, skip to Question 85.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
84a	Specify the other method of tumor sample procurement	_____	2006730	Specify the procedure performed to obtain the primary tumor tissue, if not included in the previous list.
85	Number of days from index date to date of tumor sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the tumor tissue submitted for HCMI.
86	Tumor tissue type	☐ Primary ☐ Additional Primary ☐ NOS	3288124	Provide the primary tumor tissue type for this sample.
Primary Tumor Model Information				
87	Primary model biospecimen ordinal	_____	6594596	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number is expected to be "1".***
88	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
89	BPC submitter ID (if available)		6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
90	Model represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this MODEL represent the PRIMARY DIAGNOSIS for this Case ID3?
91	Model's primary tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the PRIMARY TUMOR TISSUE from which this model is derived.
92	Model's primary tumor biospecimen ordinal	_____	6584265	Enter the biospecimen ordinal of the PRIMARY TUMOR TISSUE from which this model is derived.
Treatment Information				
93	History of neoadjuvant treatment	☐ No ☐ Yes; radiation prior to resection ☐ Yes; pharmaceutical treatment prior to resection ☐ Yes; both radiation and pharmaceutical treatment prior to resection ☐ Unknown	3382737	Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment. ***Note: Radiation therapy is addressed in Questions 101-102. Pharmaceutical therapy is addressed in Questions 95-100.***
94	Neoadjuvant chemotherapy type	☐ Cytotoxic chemotherapy ☐ Hormonal ☐ Immunotherapy (cellular and immune checkpoint) ☐ Targeted therapy (small molecule inhibitors and targeted antibodies) ☐ Not applicable	5832928	Select all neoadjuvant chemotherapy types that were administered to the patient. ***Note: Cytotoxic chemotherapy is addressed in Questions 95-96. Immunotherapy is addressed in Questions 97-98. Targeted therapy is addressed in Questions 99-100.***
95	Neoadjuvant chemotherapeutic regimen	☐ 5-Fluorouracil ☐ Albumin-bound Paclitaxel ☐ Capecitabine ☐ Cisplatin ☐ Docetaxel ☐ Folfirinox (Oxaliplatin + Leucovorin + Irinotecan + 5-FU) ☐ Gemcitabine ☐ Gemcitabine abraxane ☐ Irinotecan ☐ Irinotecan liposome ☐ Oxaliplatin ☐ Paclitaxel ☐ Other (specify)	2853313	Select all chemotherapeutics used for neoadjuvant therapy. ***Note: If neoadjuvant chemotherapy was not given, skip to Question 97. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 95a, otherwise, skip to Question 96.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
95a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapies administered.
96	Days to neoadjuvant chemotherapy treatment from index date	_____	5102411	Provide the number of days from index date to the date of treatment with neoadjuvant chemotherapy.
97	Immunotherapy name, specify	_____	2953828	Provide the name of the immunotherapy administered to the patient. ***Note: If immunotherapy was not administered, skip to Question 99.***
98	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
99	Targeted Therapy	☐ Erlotinib ☐ Other (specify)	6033149	Select the targeted molecular therapy administered to the patient. ***Note: If targeted therapy was not given, proceed to Question 101. If the targeted therapy is not listed, proceed to Question 99a, otherwise, skip to Question 100.***
99a	Specify targeted therapy	_____	4308476	Provide the name of the targeted therapy administered to the patient.
100	Days to targeted therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with targeted therapy.
101	Radiation therapy administered type	☐ 2D conventional ☐ 3D conformal ☐ Brachytherapy HDR ☐ Brachytherapy LDR ☐ IMRT ☐ Proton Beam ☐ Stereotactic Body RT ☐ Stereotactic Radiosurgery ☐ WBRT ☐ Other (specify) ☐ Unspecified ☐ Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. ***Note: If radiation therapy was not administered, proceed to Question 103. If the radiation therapy is not listed, proceed to Question 101a, otherwise, skip to Question 102.***
101a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
102	Days to radiation treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with radiation therapy.
Metastatic/Recurrent Tumor Biospecimen Information				
103	Are you submitting a metastatic/recurrent tumor tissue sample?	☐ Yes ☐ No		Indicate whether a metastatic/recurrent tumor biospecimen was collected for this ID3 case. ***Note: If yes, proceed to Question 104. If submitting an OTHER tissue sample, proceed to Question 194.***
104	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1", the second should be number "2", etc.***
105	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
106	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
107	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
108	Number of days from index date to date of diagnosis of metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic/recurrent disease.
109	Method of metastatic/ recurrent cancer sample procurement	☐ Core needle biopsy ☐ Distal partial pancreatectomy ☐ Fine needle aspiration biopsy ☐ Paracentesis ☐ Whipple procedure ☐ Other (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 109a, otherwise, skip to Question 110.***
109a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
110	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
111	Metastatic/ recurrent site	☐ Pancreatic head ☐ Pancreatic body ☐ Pancreatic tail ☐ Liver ☐ Lung ☐ Lymph node ☐ Peritoneum ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 111a, otherwise, skip to Question 112.***
111a	Other metastatic/ recurrent site	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil	3128033	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.



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		☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva		
112	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
113	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
114	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
115	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
116	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
117	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
118	Is the patient still receiving treatment?	_____	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
119	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
120	Number of peripancreatic lymph nodes tested at surgery	_____	6050944	Provide the total number of peripancreatic lymph nodes tested for the presence of pancreatic cancer cells.
121	Number of positive peripancreatic lymph nodes	☐ 0 ☐ 1-3 ☐ ≥4 ☐ Unknown	5983082	Select the numeric range of the number of peripancreatic lymph nodes that tested positive for the presence of pancreatic cancer cells.
122	Has the CEA level of the patient been determined?	☐ Yes ☐ No	3107563	Indicate whether the Carcinoembryonic antigen (CEA) level of the patient has been determined. ***Note: If the patient's CEA level has not been determined, skip to Question 125.***
123	CEA level	_____	2752	Provide the patient's carcinoembryonic (CEA) level (ng/ml).



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
124	CEA level upper limit of normal value	_____	2002247	Provide the numeric laboratory value (ng/ml) representing the upper level of the normal range of values for carcinoembryonic antigen (CEA) in blood used to comparatively reference the patient's lab result.
125	Was tumor marker CA-19-9 test performed?	☐ Yes ☐ No ☐ Unknown	2891778	Indicate whether the patient's tumor marker CA-19-9 value was assessed. ***Note: If the CA-19-9 test was not performed, skip to Question 127.***
126	What was the CA-19-9 value?	_____	65302	Provide the patient's CA-19-9 level.
Metastatic/Recurrent Tumor Sample: Clinical Molecular Analyses				
127	Was KRAS mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6060079	Indicate whether KRAS mutation analysis was performed. ***Note: If not performed, skip to Question 130.***
128	Was a mutation in KRAS identified	☐ Yes ☐ No	6060081	Indicate whether a mutation in KRAS was identified through mutation analysis. ***Note: If mutation was not identified, skip to Question 130.***
129	If KRAS mutation identified, which one?	☐ G12A ☐ G12C ☐ G12D ☐ G12R ☐ G12S ☐ G12V ☐ G13D ☐ G13R ☐ G13C ☐ G13A ☐ G13V ☐ Q61L ☐ Q61H ☐ A146T ☐ Other (specify)	6060083	Indicate the specific KRAS mutation identified. ***Note: If the KRAS mutation is not listed, proceed to Question 129a, otherwise, skip to Question 130.***
129a	Other KRAS mutation(s)	_____	6101691	If the KRAS mutation identified is not provided in the previous list, specify the KRAS mutation.
130	Was TP53 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063448	Indicate whether TP53 mutation analysis was performed. ***Note: If not performed, skip to Question 132.***
131	If TP53 mutation identified, which one?	☐ R175H ☐ R213L ☐ Y220C ☐ C238Y ☐ G245D ☐ G245S ☐ R248Q ☐ R248W ☐ G266E ☐ G266V ☐ V272M ☐ R273C ☐ R273H ☐ R273L ☐ R282G ☐ R282W ☐ Other (specify)	6063731	Indicate the specific TP53 mutation identified. ***Note: If the TP53 mutation is not listed, proceed to Question 131a, otherwise, skip to Question 132.***
131a	Other TP53 mutation(s)	_____	6101683	If the TP53 mutation identified is not provided in the previous list, specify the TP53 mutation.
132	Was CDKN2A mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063449	Indicate whether CDKN2A mutation analysis was performed. ***Note: If not performed, skip to Question 135.***
133	Was a mutation in CDKN2A identified?	☐ Yes ☐ No	6063534	Indicate whether a mutation in CDKN2A was identified through mutation analysis. ***Note: If mutation was not identified, skip to Question 135.***
134	If CDKN2A mutation identified, which one?	☐ A30V ☐ V51D ☐ V51I ☐ H83P ☐ H83Y ☐ D108H ☐ D108Y ☐ L130Q ☐ A147T ☐ A148T ☐ Other (specify)	6063732	Indicate the specific CDKN2A mutation identified. ***Note: If the CDKN2A mutation is not listed, proceed to Question 134a, otherwise, skip to Question 135.***
134a	Other CDKN2A mutation(s)	_____	6101684	If the CDKN2A mutation identified is not provided in the previous list, specify the CDKN2A mutation.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
135	Was GNAS mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063450	Indicate whether GNAS mutation analysis was performed. ***Note: If not performed, skip to Question 138.***
136	Was a mutation in GNAS identified?	☐ Yes ☐ No	5983161	Indicate whether a mutation in GNAS was identified through mutation analysis. ***Note: If mutation was not identified, skip to Question 138.***
137	If GNAS mutation identified, which one?	☐ Q125R ☐ R160C ☐ R201C ☐ R201H ☐ R201S ☐ Q227E ☐ Q227L ☐ Q227P ☐ Q227R ☐ Other (specify)	6063733	Indicate the specific GNAS mutation identified. ***Note: If the GNAS mutation is not listed, proceed to Question 137a, otherwise, skip to Question 138.***
137a	Other GNAS mutation(s)	_____	6101685	If the GNAS mutation identified is not provided in the previous list, specify the GNAS mutation.
138	Was RNF43 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063451	Indicate whether RNF43 mutation analysis was performed. ***Note: If not performed, skip to Question 141.***
139	Was a mutation in RNF43 identified?	☐ Yes ☐ No	5983286	Indicate whether a mutation in RNF43 was identified through mutation analysis. ***Note: If mutation was not identified, skip to Question 140.***
140	If RNF43 mutation identified, which one?	☐ R127P ☐ D140E ☐ P154L ☐ A169T ☐ E318D ☐ Other (specify)	6063734	Indicate the specific RNF43 mutation identified. ***Note: If the RNF43 mutation is not listed, proceed to Question 140a, otherwise, skip to Question 141.***
140a	Other RNF43 mutation(s)	_____	6101686	If the RNF43 mutation identified is not provided in the previous list, specify the RNF43 mutation.
141	Was SMAD4 IHC performed?	☐ Yes ☐ No ☐ Unknown	6063646	Indicate whether SMAD4 protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If not performed, skip to Question 143.***
142	SMAD4 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063676	Indicate the status of SMAD4 protein expression as determined by immunohistochemistry (IHC).
Additional Metastatic/Recurrent Tumor Biospecimen Information (if applicable)				
143	Are you submitting an additional metastatic/ recurrent tumor tissue sample?	☐ Yes ☐ No		A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen. ***Note: If yes, proceed to Question 144, otherwise, skip to Question 183.***
144	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. The first biospecimen should be number "1," the second should be number "2," etc.
145	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
146	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
147	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
148	Number of days from index date to date of diagnosis of additional metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of additional metastatic/recurrent disease.
149	Method of metastatic/ recurrent cancer sample procurement	☐ Core needle biopsy ☐ Distal partial pancreatectomy ☐ Fine needle aspiration biopsy ☐ Paracentesis ☐ Whipple procedure ☐ Other (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 149a, otherwise, skip to Question 150.***
149a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
150	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
151	Metastatic/ recurrent site	☐ Pancreatic head ☐ Pancreatic body ☐ Pancreatic tail ☐ Liver ☐ Lung ☐ Lymph node ☐ Peritoneum ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 151a, otherwise, skip to Question 152.***
151a	Other metastatic/ recurrent site	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.



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		☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva		
152	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
153	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
154	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
155	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
156	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
157	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
158	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
159	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
160	Number of peripancreatic lymph nodes tested at surgery	_____	6050944	Provide the total number of peripancreatic lymph nodes tested for the presence of pancreatic cancer cells.
161	Number of positive peripancreatic lymph nodes	☐ 0 ☐ 1-3 ☐ ≥4 ☐ Unknown	5983082	Select the numeric range of the number of peripancreatic lymph nodes that tested positive for the presence of pancreatic cancer cells.
162	Has the CEA level of the patient been determined?	☐ Yes ☐ No	3107563	Indicate whether the Carcinoembryonic antigen (CEA) level of the patient has been determined. ***Note: If the patient's CEA level has not been determined, skip to Question 165.***
163	CEA level	_____	2752	Provide the patient's carcinoembryonic (CEA) level (ng/ml).



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
164	CEA level upper limit of normal value	_____	2002247	Provide the numeric laboratory value (ng/ml) representing the upper level of the normal range of values for carcinoembryonic antigen (CEA) in blood used to comparatively reference the patient's lab result.
165	Was tumor marker CA-19-9 test performed?	☐ Yes ☐ No ☐ Unknown	2891778	Indicate whether the patient's tumor marker CA-19-9 value was assessed. ***Note: If the CA-19-9 test was not performed, skip to Question 167.***
166	What was the CA-19-9 value?	_____	65302	Provide the patient's CA-19-9 level.
Additional Metastatic/Recurrent Tumor Sample: Clinical Molecular Analyses				
167	Was KRAS mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6060079	Indicate whether KRAS mutation analysis was performed. ***Note: If not performed, skip to Question 170.***
168	Was a mutation in KRAS identified	☐ Yes ☐ No	6060081	Indicate whether a mutation in KRAS was identified through mutation analysis. ***Note: If mutation was not identified, skip to Question 170.***
169	If KRAS mutation identified, which one?	☐ G12A ☐ G12C ☐ G12D ☐ G12R ☐ G12S ☐ G12V ☐ G13D ☐ G13R ☐ G13C ☐ G13A ☐ G13V ☐ Q61L ☐ Q61H ☐ A146T ☐ Other (specify)	6060083	Indicate the specific KRAS mutation identified. ***Note: If the KRAS mutation is not listed, proceed to Question 169a, otherwise, skip to Question 170.***
169a	Other KRAS mutation(s)	_____	6101691	If the KRAS mutation identified is not provided in the previous list, specify the KRAS mutation.
170	Was TP53 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063448	Indicate whether TP53 mutation analysis was performed. ***Note: If not performed, skip to Question 172.***
171	If TP53 mutation identified, which one?	☐ R175H ☐ R213L ☐ Y220C ☐ C238Y ☐ G245D ☐ G245S ☐ R248Q ☐ R248W ☐ G266E ☐ G266V ☐ V272M ☐ R273C ☐ R273H ☐ R273L ☐ R282G ☐ R282W ☐ Other (specify)	6063731	Indicate the specific TP53 mutation identified. ***Note: If the TP53 mutation is not listed, proceed to Question 171a, otherwise, skip to Question 172.***
171a	Other TP53 mutation(s)	_____	6101683	If the TP53 mutation identified is not provided in the previous list, specify the TP53 mutation.
172	Was CDKN2A mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063449	Indicate whether CDKN2A mutation analysis was performed. ***Note: If not performed, skip to Question 176.***
173	Was a mutation in CDKN2A identified?	☐ Yes ☐ No	6063534	Indicate whether a mutation in CDKN2A was identified through mutation analysis. ***Note: If mutation was not identified, skip to Question 175.***
174	If CDKN2A mutation identified, which one?	☐ A30V ☐ V51D ☐ V51I ☐ H83P ☐ H83Y ☐ D108H ☐ D108Y ☐ L130Q ☐ A147T ☐ A148T ☐ Other (specify)	6063732	Indicate the specific CDKN2A mutation identified. ***Note: If the CDKN2A mutation is not listed, proceed to Question 174a, otherwise, skip to Question 175.***
174a	Other CDKN2A mutation(s)	_____	6101684	If the CDKN2A mutation identified is not provided in the previous list, specify the CDKN2A mutation.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
175	Was GNAS mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063450	Indicate whether GNAS mutation analysis was performed. ***Note: If not performed, skip to Question 178.***
176	Was a mutation in GNAS identified?	☐ Yes ☐ No	5983161	Indicate whether a mutation in GNAS was identified through mutation analysis. ***Note: If mutation was not identified, skip to Question 178.***
177	If GNAS mutation identified, which one?	☐ Q125R ☐ R160C ☐ R201C ☐ R201H ☐ R201S ☐ Q227E ☐ Q227L ☐ Q227P ☐ Q227R ☐ Other (specify)	6063733	Indicate the specific GNAS mutation identified. ***Note: If the GNAS mutation is not listed, proceed to Question 177a, otherwise, skip to Question 178.***
177a	Other GNAS mutation(s)	_____	6101685	If the GNAS mutation identified is not provided in the previous list, specify the GNAS mutation.
178	Was RNF43 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6063451	Indicate whether RNF43 mutation analysis was performed. ***Note: If not performed, skip to Question 181.***
179	Was a mutation in RNF43 identified?	☐ Yes ☐ No	5983286	Indicate whether a mutation in RNF43 was identified through mutation analysis. ***Note: If mutation was not identified, skip to Question 181.***
180	If RNF43 mutation identified, which one?	☐ R127P ☐ D140E ☐ P154L ☐ A169T ☐ E318D ☐ Other (specify)	6063734	Indicate the specific RNF43 mutation identified. ***Note: If the RNF43 mutation is not listed, proceed to Question 180a, otherwise, skip to Question 181.***
180a	Other RNF43 mutation(s)	_____	6101686	If the RNF43 mutation identified is not provided in the previous list, specify the RNF43 mutation.
181	Was SMAD4 IHC performed?	☐ Yes ☐ No ☐ Unknown	6063646	Indicate whether SMAD4 protein expression by immunohistochemistry (IHC) analysis was performed. ***Note: If not performed, skip to Question 183.***
182	SMAD4 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063676	Indicate the status of SMAD4 protein expression as determined by immunohistochemistry (IHC).
Metastatic/Recurrent Tumor Model Information				
183	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
184	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
185	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
186	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
187	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.



Enrollment: Pancreas

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Additional Metastatic/Recurrent Biospecimen Tumor Model Information (if applicable)				
188	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
189	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
190	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
191	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
192	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Other Biospecimen Information				
193	Are you submitting an OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an OTHER tissue sample (e.g. pre-malignant, non-malignant, or dysplastic tissue, etc.) was collected for HCMI for this case. ***Note: If yes, proceed to Question 194.***
194	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
195	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
196	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
197	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
198	Other method of cancer sample procurement	☐ Core needle biopsy ☐ Distal partial pancreatectomy ☐ Fine needle aspiration biopsy ☐ Paracentesis ☐ Whipple procedure ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 198a, otherwise, skip to Question 199.***
198a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.



Enrollment: Pancreas

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
199	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
200	Tissue type	☐ Non-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 200a, otherwise, skip to Question 201.***
200a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
201	Anatomic site of OTHER tissue	☐ Pancreatic head ☐ Pancreatic body ☐ Pancreatic tail ☐ Liver ☐ Lung ☐ Lymph node ☐ Peritoneum ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 201a, otherwise, skip to Question 202.***
201a	Specify anatomic site of OTHER tissue	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	6584916	Specify the site of OTHER tissue, if not in the previous list.
202	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
203	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.



Enrollment: Pancreas

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Additional OTHER biospecimen Information (if applicable)				
204	Are you submitting an additional OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an additional OTHER tissue sample (pre-malignant, non-malignant, or dysplastic tissue, etc.) is being submitted for HCMI for this case. ***Note: If yes, proceed to Question 205, otherwise, skip to Question 215.***
205	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
206	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
207	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
208	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
209	Other method of cancer sample procurement	☐ Core needle biopsy ☐ Distal partial pancreatectomy ☐ Fine needle aspiration biopsy ☐ Paracentesis ☐ Whipple procedure ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 209a, otherwise, skip to Question 210.***
209a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
210	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
211	Tissue type	☐ Non-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 211a, otherwise, skip to Question 212.***
211a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
212	Anatomic site of OTHER tissue	☐ Pancreatic head ☐ Pancreatic body ☐ Pancreatic tail ☐ Liver ☐ Lung ☐ Lymph node ☐ Peritoneum ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 212a, otherwise, skip to Question 213.***
212a	Specify anatomic site of OTHER tissue	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum	6584916	Specify the site of OTHER tissue, if not in the previous list.



Enrollment: Pancreas

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

		and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva		
213	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
214	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Other Tissue Model Information				
215	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
216	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
217	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
218	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
209	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.
Additional Other Tissue Model Information (if applicable)				
220	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
221	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
222	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
223	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
224	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.



Enrollment: Pediatric Liver

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Form Notes: An Enrollment Form should be completed for each HCMI case upon qualification notice from Leidos. All information provided on this form should include activity from the Date of Initial Pathologic Diagnosis to the most recent Date of Last Contact with the patient.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	☐ Initial pathologic diagnosis ☐ Sample procurement ☐ First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.
Normal Control Information				
4	Type of normal control	☐ Whole blood ☐ Buccal cells ☐ Buffy coat ☐ Lymphocytes ☐ Extracted DNA from blood ☐ Extracted DNA from saliva ☐ Extracted DNA from buccal cells ☐ Extracted DNA from normal tissue ☐ FFPE non-neoplastic tissue ☐ Non-neoplastic tissue	3081936	Indicate the type of normal control submitted for this case.
Tumor Tissue Collected for Molecular Characterization, Sample Information				
5	Tumor tissue sample preservation method	☐ FFPE ☐ Fresh ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the tumor tissue sample collected to be used for molecular characterization.
Cancer Model Information				
6	Anatomic site of tumor from which model was derived	☐ Ascites ☐ Bone ☐ Brain ☐ Liver ☐ Lung ☐ Lymph node ☐ Other (specify)	4214629	Indicate the anatomic site of the tumor tissue used to generate the model for the HCMI. ***Note: If the anatomic site of tumor tissue is not listed, proceed to Question 6a, otherwise, skip to Question 7.***
6a	Other anatomic site	_____	5946219	If the anatomic site for the tumor submitted to HCMI is not included on the provided list, specify the anatomic site.
7	Method of cancer sample procurement	☐ Core needle biopsy ☐ Excisional biopsy ☐ Fine needle aspiration ☐ Incisional biopsy ☐ Tumor resection ☐ Other (specify)	3103514	Indicate the procedure performed to obtain the tumor tissue used to generate the model for HCMI. ***Note: If the method of sample procurement is not listed, proceed to Question 7a, otherwise, skip to Question 8.***
7a	Other method of sample procurement	_____	2006730	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
8	Number of days from index date to date of cancer sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the tumor tissue submitted for HCMI.



Enrollment: Pediatric Liver

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
9	ICD-10 code for model tumor	☐ C22.0 ☐ C22.1 ☐ C22.2 ☐ C22.3 ☐ C22.4 ☐ C22.7 ☐ C22.8 ☐ C22.9 ☐ C77.9 ☐ C78.0 ☐ C79.3 ☐ C79.5 ☐ Other (specify)	3226287	Provide the ICD-10 code for the tumor used to generate the model submitted to HCMI. ***Note: If the ICD-10 code is not listed, proceed to Question 9a, otherwise, skip to Question 10.***
9a	Other ICD-10 code	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.
10	Tumor tissue type	☐ Premalignant ☐ Primary ☐ Recurrent ☐ Metastatic ☐ Additional primary ☐ NOS	3288124	Provide the tumor tissue type for the biospecimen used to produce the model for the HCMI. ***Note: If 'Metastatic' is selected, continue to answer through Question 18. If the tissue is not 'Metastatic', skip to Question 19.***
Metastatic Model Information *(only complete Questions 11-18 if 'Metastatic' was selected in Question 10)*				
11	Age at diagnosis of metastasis	_____	6032752	Provide the age (in days) of the patient when diagnosed with metastatic disease. If the patient's age is greater than 32,507 days (89 years), please enter 32,507.
12	Number of days from index date to date of diagnosis of metastasis	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic disease.
13	Metastatic site	☐ Lung ☐ Brain ☐ Bone ☐ Lymph node(s) ☐ Lymph node(s) - distant ☐ Other (specify)	6119068	Select the site from which the metastatic tissue used to develop the model was derived. ***Note: If the metastatic site is not listed, proceed to Question 13a, otherwise, skip to Question 14.***
13a	Other metastatic site	_____	3128033	If not included in the previous list, specify the site from which the metastatic tissue used to develop the model was derived.
14	Maintenance and/or consolidation therapy administered prior to collection of metastatic tissue	_____	6119066	If applicable, provide the name of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic tissue used to develop the model. ***Note: If maintenance and/or consolidation therapy was not administered, skip to Question 19.***
15	Days from index date to start of maintenance and/or consolidation therapy	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
16	Days from index date to last known date of maintenance and/or consolidation therapy treatment	_____	65167	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.



Enrollment: Pediatric Liver

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
17	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing treatment.
18	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
Patient Information				
19	Gender	☐ Male ☐ Female ☐ Unspecified	2200604	Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
20	Height	_____	649	Provide the patient's height, in centimeters.
21	Weight	_____	651	Provide the patient's weight, in kilograms.
22	Body mass index (BMI)	_____	2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
23	Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown ☐ Not allowed to collect	2192199	Provide the patient's race using the defined categories. **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 peoples of the Far East, Southeast Asia, or in the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Phillippine Islands, Thailand, and Vietnam. **Black or African American:** A person having origins in any of the black racial groups of Africa. **Native Hawaiian or other Pacific Islander:** A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island. **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
24	Ethnicity	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Not allowed to collect	2192217	Provide the patient's ethnicity using the defined categories. **Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. **Not Hispanic or Latino:** A person not meeting the definition of Hispanic or Latino.
25	Year of birth	_____	2896954	Provide the year of the patient's birth. If the patient was born prior to 1928, insert the date 1928.
26	Family history of cancer	☐ Same ☐ Different ☐ None ☐ Unknown	5832923	Has a first-degree relative of the patient been diagnosed with a cancer of the same or a different type?
27	Tobacco smoking history	☐ Lifelong non-smoker (<100 cigarettes smoked in a lifetime) ☐ Current smoker (includes daily and non-daily smokers) ☐ Current reformed smoker (duration not specified) ☐ Current reformed smoker for >15 years ☐ Current reformed smoker for ≤15 years	2181650	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories.



Enrollment: Pediatric Liver

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Primary Tumor Diagnosis Information				
28	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.
29	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. If the patient's age is greater than 32,507 days (89 years), please enter 32,507.
30	Morphology	☐ 8170/3 (Hepatocellular carcinoma, NOS) ☐ 8171/3 (Hepatocellular carcinoma, fibrolamellar) ☐ 8970/3 (Hepatoblastoma) ☐ 8991/3 (Embryonal sarcoma) ☐ Other (specify)	3226275	Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor. ***Note: If the morphology is not listed, proceed to Question 30a, otherwise, skip to Question 31.***
30a	Other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.
31	Tissue or organ of origin	☐ Liver ☐ Other (specify)	3427536	Using the patient's pathology/laboratory report, select the primary site of the disease. ***Note: If the tissue or organ of origin is not listed, proceed to Question 31a, otherwise, skip to Question 32.***
31a	Other tissue or organ of origin	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	3427536	If the primary site of the disease is not included on the previous list, select the primary site of the disease.



Enrollment: Pediatric Liver

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
32	Histological type	_____	3294805	Provide the traditional surgical pathology text description of the histological tumor type.
33	If hepatoblastoma, specify histology	☐ Fetal/embryonal ☐ Mesenchymal/macrotrabecular ☐ Mixed epithelial ☐ Small cell undifferentiated ☐ Well differentiated fetal ☐ Unknown ☐ Not applicable	4908981	If the liver cancer is hepatoblastoma, specify the histology.
34	If hepatocellular carcinoma, specify histology	☐ Fibrolamellar ☐ Hepatocellular NOS ☐ Unknown ☐ Not applicable	4908996	If the liver cancer is hepatocellular carcinoma, specify the histology.
35	Prior malignancy (of the same cancer type)	☐ Yes ☐ No ☐ Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
36	Prior malignancy (other cancer type)	☐ Yes ☐ No ☐ Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.
37	Tumor stage	☐ I ☐ II ☐ III ☐ IV	6013618	Provide the stage of the tumor using the PRETEXT staging system.
38	Metastasis at diagnosis assessment status	☐ Metastatic ☐ Non-metastatic (confirmed) ☐ Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor.
39	Metastatic site(s) at diagnosis	☐ Lung ☐ Brain ☐ Bone ☐ Lymph node(s) ☐ Lymph node(s) - distant ☐ Other (specify)	3029815	Indicate all the site(s) of metastasis at the time of diagnosis of the primary tumor. ***Note: If the metastatic site(s) is not listed, proceed to Question 39a, otherwise, skip to Question 40.***
39a	Specify metastatic site(s)	_____	3128033	If the site(s) of metastasis at the time of diagnosis of the primary tumor is not included in the provided list, specify the site(s).
40	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, select all sites of relapse. ***Note: If the primary tumor did not relapse, select 'Not applicable'.***
Prognostic/Predictive/Lifestyle Features for Tumor Prognosis or Responsiveness to Treatment				
41	Premature birth (born <37 weeks gestation)?	☐ Yes ☐ No ☐ Unknown	6010765	Indicate whether the patient was born at less than 37 weeks gestation. ***Note: If not born prematurely, skip to Question 43.***
42	Weeks gestation at birth	_____	2737369	Specify the number of weeks of gestation at which the patient was born.
43	Genetic predisposition mutation known?	☐ Yes ☐ No ☐ Unknown	2665140	Indicate whether the patient has a known genetic predisposition mutation. ***Note: If the genetic predisposition mutation is not known, skip to Question 45.***
44	Genetic predisposition mutation	☐ APC ☐ P53 ☐ Other (specify)	6010766	Select the patient's known genetic predisposition mutation. ***Note: If the mutation is not listed, proceed to Question 44a, otherwise, skip to Question 45.***



Enrollment: Pediatric Liver

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
44a	Other genetic predisposition mutation	_____	2772026	If the patient's genetic predisposition mutation is not included on the previous list, specify the patient's other known genetic predisposition mutation.
45	Does the patient have genetic syndrome(s)?	☐ Yes ☐ No ☐ Unknown	4917534	Indicate whether the patient has any genetic syndromes. ***Note: If the patient does not have a genetic syndrome, skip to Question 47.***
46	Syndrome(s) diagnosed	☐ Alpha-1 antitrypsin ☐ Glycogen storage disease ☐ Biliary abnormality ☐ Tyrosinemia ☐ Cirrhosis without an underlying etiology ☐ Beckwidth-Wiedemann ☐ Other (specify)	6013458	Select the patient's diagnosed genetic syndrome(s). ***Note: If the syndrome is not listed, proceed to Question 46a, otherwise, skip to Question 47.***
46a	Other syndrome diagnosed	_____	64158	If the patient's genetic syndrome is not included in the provided list, please specify the patient's other genetic syndrome.
47	Infection history?	☐ Yes ☐ No ☐ Unknown	2816879	Indicate whether the patient has a history of relevant infectious disease. ***Note: If the patient does not have relevant infection history, skip to Question 49.***
48	Name of relevant infectious disease	☐ Hepatitis A ☐ Hepatitis B ☐ Hepatitis C	3233642	Indicate the name of the relevant infectious disease.
49	Upper limit of normal range for the Alpha-Fetoprotein level	_____	2932064	Provide the upper limit of normal for alpha-fetoprotein in ng/mL.
50	Lower limit of normal range for the Alpha-Fetoprotein level	_____	3171861	Provide the lower limit of normal for alpha-fetoprotein in ng/mL.
51	Alpha-Fetoprotein level (0-10 million ng/mL) at diagnosis	_____	2932074	Provide the numerical laboratory result for alpha-fetoprotein in ng/mL.
Treatment Information				
52	History of neoadjuvant treatment	☐ No ☐ Yes; radiation prior to resection ☐ Yes; pharmaceutical treatment prior to resection ☐ Yes; both radiation and pharmaceutical treatment prior to resection ☐ Unknown	3382737	Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment. ***Note: Radiation therapy is addressed in Questions 60-61. Pharmaceutical therapy is addressed in Questions 53-59.***
53	Neoadjuvant chemotherapy type	☐ Cytotoxic chemotherapy ☐ Hormonal ☐ Immunotherapy (cellular and immune checkpoint) ☐ Targeted therapy (small molecule inhibitors and targeted antibodies) ☐ Not applicable	5832928	Select all neoadjuvant chemotherapy types that were administered to the patient. ***Note: Cytotoxic chemotherapy is addressed in Questions 54-55. Immunotherapy is addressed in Questions 56-57. Targeted therapy is addressed in Questions 58-59.***



Enrollment: Pediatric Liver

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
54	Neoadjuvant chemotherapeutic regimen	☐ 5-fluorouracil ☐ Carboplatin ☐ Cisplatin ☐ Doxorubicin ☐ Etoposide ☐ Ifosfamide ☐ Pirarubicin ☐ Vincristine ☐ Vinorelbine ☐ Vincristine, actinomycin-D, cyclophosphamide (VAC) ☐ Vincristine, doxorubicin, cyclophosphamide, ifosfamide, etoposide (VDC/IE) ☐ Vincristine, actinomycin-D, cyclophosphamide, vincristine, irinotecan (VAC/VI) ☐ Ifosfamide, carboplatin, etoposide (ICE) ☐ Vincristine, irinotecan, temozolomide (VIT) ☐ High-dose methotrexate, doxorubicin, cisplatin (MAP) ☐ Other (specify) ☐ Chemotherapy not given	2853313	Select all chemotherapeutics used for neoadjuvant therapy. ***Note: If neoadjuvant chemotherapy was not given, skip to Question 49. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 47a, otherwise, skip to Question 48.***
54a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapy.
55	Days to neoadjuvant chemotherapy treatment from index date	_____	5102411	Provide the number of days from index date to the date of treatment with neoadjuvant chemotherapy.
56	Immunotherapy name, specify	_____	2185614	Specify the name of the immunotherapy administered. ***Note: If immunotherapy was not given, skip to Question 51.***
57	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
58	Targeted therapy	☐ Sorafenib ☐ Other (specify)	6010754	Select the targeted therapy administered to the patient. ***Note: If targeted therapy was not given, skip to Question 53. If the targeted therapy is not listed, proceed to Question 58a, otherwise, skip to Question 59.***
58a	Other targeted therapy	_____	4308476	If the targeted therapy is not included in the provided list, specify targeted therapy.
59	Days to targeted therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with targeted therapy.



Enrollment: Pediatric Liver

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
60	Radiation therapy administered type	☐ 2D conventional ☐ 3D conformal ☐ Brachytherapy HDR ☐ Brachytherapy LDR ☐ IMRT ☐ Proton Beam ☐ Stereotactic Body RT ☐ Stereotactic Radiosurgery ☐ WBRT ☐ Other (specify) ☐ Unspecified ☐ Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. ***Note: If radiation therapy was not administered, skip the remaining questions. If the radiation therapy is not listed, proceed to Question 60a, otherwise, skip to Question 61.***
60a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
61	Days to radiation treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with radiation therapy.



Enrollment: Prostate

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Form Notes: An Enrollment Form should be completed for each HCMI case upon qualification notice from Leidos. All information provided on this form should include activity from the Date of Initial Pathologic Diagnosis to the most recent Date of Last Contact with the patient.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	☐ Initial pathologic diagnosis ☐ Sample procurement ☐ First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.
Patient Information				
4	Gender	☐ Male ☐ Female ☐ Unspecified	2200604	Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
5	Height	_____	649	Provide the patient's height, in centimeters.
6	Weight	_____	651	Provide the patient's weight, in kilograms.
7	Body mass index (BMI)	_____	2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
8	Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown ☐ Not reported	2192199	Provide the patient's race using the defined categories. **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 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. **Black or African American:** A person having origins in any of the black racial groups of Africa. **Native Hawaiian or other Pacific Islander:** A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island. **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
9	Ethnicity	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Not reported	2192217	Provide the patient's ethnicity using the defined categories. **Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. **Not Hispanic or Latino:** A person not meeting the definition of Hispanic or Latino.



Enrollment: Prostate

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
10	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.
11	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. ***Note: If the patient's age is greater than 32,872 days (90 years), please enter 32,872.***
12	Year of birth	_____	2896954	Provide the year of the patient's birth. If the patient was born prior to 1928, insert the date 1928.
13	Family history of cancer	☐ Same ☐ Different ☐ None ☐ Unknown	5832923	Has a first-degree relative of the patient been diagnosed with a cancer of the same or a different type?
14	Smoking history	☐ Lifelong non-smoker (<100 cigarettes smoked in a lifetime) ☐ Current smoker (includes daily and non-daily smokers) ☐ Current reformed smoker (duration not specified) ☐ Current reformed smoker for >15 years ☐ Current reformed smoker for ≤15 years	2181650	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories.
15	Clinical history (select all that apply)	☐ BRCA1/2 family history ☐ Hereditary prostate cancer ☐ Lynch syndrome ☐ Not applicable ☐ Other (specify)	6690684	Select all relevant prior diseases/disorders in the patient's clinical history. ***Note: If the clinical history is not listed, proceed to Question 15a, otherwise, skip to Question 16.***
15a	Other clinical history	_____	6690685	If not included in the previous list, specify other relevant prior diseases/disorders in the patient's clinical history.
16	Metastasis at diagnosis assessment status	☐ Metastatic ☐ Non-metastatic (confirmed) ☐ Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor. ***Note: If metastatic at diagnosis, proceed to Question 17, otherwise, skip to Question 18.***
17	Metastatic site(s) at diagnosis	☐ Lung ☐ Bone ☐ Liver ☐ Brain ☐ Lymph node(s): distant ☐ Lymph node(s): regional ☐ Other (specify)	3029815	Indicate the site(s) of metastasis at the time of diagnosis of the primary tumor. ***Note: If the anatomic site of tumor tissue is not listed, proceed to Question 17a, otherwise, skip to Question 18.***
17a	Specify metastatic site(s)	_____	3128033	If the site of metastasis is not included on the provided list, specify the site of metastasis.
Biospecimen Information				
18	Tissue sample type(s) collected for HCMI for this case	☐ Normal tissue ☐ Primary tumor ☐ Metastatic ☐ Recurrent ☐ Other tissue	2006911	Please select all the tissue sample types submitted for HCMI with this case.
19	Number of NORMAL tissues biospecimens collected for HCMI for this case	_____	6584256	Please provide the number of normal tissue specimens obtained for HCMI for this case. ***Note: This number is expected to be 1.***



Enrollment: Prostate

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
20	Number of PRIMARY cancer tissue biospecimens collected for HCMI model development for this case	_____	6584257	Please provide the number of primary tumor specimens obtained for HCMI for this case. ***Note: A single primary tumor biospecimen obtained that is portioned for both sequencing and model generation counts as 1 single primary tumor specimen. This number is expected to be 1.***
21	Number of METASTATIC/RECURRENT cancer tissue biospecimens collected for HCMI model development for this case	_____	6584258	Please provide the number of metastatic and/or recurrent cancer biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
22	Number of OTHER tissue biospecimens collected for HCMI model development for this case	_____	6584259	Please provide the number of pre-malignant, non-malignant, or dysplastic tissue biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
23	Total number of tissue biospecimens collected for HCMI for this case	_____	6584271	Please provide the total number of tissue biospecimens collected for HCMI for this case. ***Note: This number should be the sum of the normal, primary tumor, metastatic/ recurrent tumor, and other biospecimen counts above.***
Normal Control Information				
24	Normal tissue biospecimen ordinal	_____	6584264	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
25	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
26	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
27	Type of normal control	☐ Whole blood ☐ Buccal cells ☐ Buffy coat ☐ Lymphocytes ☐ Extracted DNA from blood ☐ Extracted DNA from saliva ☐ Extracted DNA from buccal cells ☐ Extracted DNA from normal tissue ☐ FFPE non-neoplastic tissue ☐ Non-neoplastic tissue	3081936	Indicate the type of normal control submitted for this case.



Enrollment: Prostate

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
28	Anatomic site of normal tissue	☐ Lymph node(s) ☐ Skin ☐ Other (specify) ☐ Not applicable	4132152	If non-neoplastic tissue was submitted as the normal control, select the anatomic site of the normal tissue. ***Note: If the anatomic site of normal tissue is not listed, proceed to Question 28a, otherwise, skip to Question 29.***
28a	Other anatomic site of normal tissue	_____	3288189	If non-neoplastic tissue, adjacent tissue, or normal tissue from another anatomic site was submitted as the normal control, provide the anatomic site of the normal tissue.
29	Distance from tumor to normal control tissue (if not blood)	☐ Adjacent (< or = 2cm) ☐ Distal (>2cm) ☐ Unknown ☐ Not applicable	3088708	Indicate the distance from the site of normal tumor collection to the primary tumor. ***Note: If normal tissue was not submitted, select 'Not applicable'.***
30	Normal tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the normal tissue sample collected for molecular characterization.
Primary Tumor Biospecimen Information				
31	ICD-10 code for primary tumor	☐ C61 ☐ Other (specify)	3226287	Provide the ICD-10 code for the primary tumor as used to generate the ID3 for this subject. ***Note: If the ICD-10 code is not listed, proceed to 31a, otherwise, skip to Question 32.***
31a	Other ICD-10 code for primary tumor	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.
32	Tumor morphology	☐ 8041/3 ☐ 8140/3 ☐ 8500/3 ☐ 8574/3 ☐ Other (specify)	3226275	Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor. ***Note: If the ICD-O-3 histology code of the primary tumor is not listed, proceed to Question 32a, otherwise, skip to Question 33.***
32a	Specify other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.
33	Tissue or organ of origin	☐ Prostate ☐ Other (specify)	3427536	Using the patient's pathology/laboratory report, select the primary site of the disease. ***Note: If the primary site of the disease is not listed, proceed to Question 33a, otherwise skip to Question 34.***
33a	Other tissue or organ of origin	_____	5946219	If the primary site of the disease is not included on the previous list, provide the primary site of the disease.
34	Histological type	☐ Prostate cancer ☐ Other (specify)	3081932	Select the surgical pathology text description of the histological tumor type. ***Note: If the histological tumor type is not listed, proceed to Question 34a, otherwise, skip to Question 35.***



Enrollment: Prostate

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
34a	Other histological type	_____	3294805	If the traditional surgical pathology text description of the histological tumor type is not included on the previous list, please specify the histological type.
35	Histological subtype	☐ Acinar adenocarcinoma ☐ Ductal adenocarcinoma ☐ Small-cell neuroendocrine carcinoma ☐ Isolated intraductal carcinoma ☐ Neuroendocrine prostate carcinoma (NEPC) ☐ Other (specify)	3081934	Using the patient's pathology/laboratory report, select the histological subtype of the primary tumor. ***Note: If the histological subtype is not listed, proceed to Question 35a, otherwise, skip to Question 36.***
35a	Other histological subtype	_____	3124492	If the histological subtype for the primary tumor is not included in the provided list, specify the histological subtype.
36	Prior malignancy (of the same cancer type)	☐ Yes ☐ No ☐ Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
37	Prior malignancy (other cancer type)	☐ Yes ☐ No ☐ Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.
38	AJCC cancer staging edition	☐ 1st ☐ 5th ☐ 2nd ☐ 6th ☐ 3rd ☐ 7th ☐ 4th ☐ 8th	2722309	Select the AJCC staging handbook edition used to stage the patient's primary tumor.
39	AJCC pathologic spread: Primary tumor (pT)	☐ T2 ☐ T3 ☐ T2a ☐ T3a ☐ T2b ☐ T3b ☐ T2c ☐ T4	3045435	Using the patient's pathology/laboratory report, select the code for the pathologic T (primary tumor) as defined by the American Joint Committee on Cancer (AJCC).
40	AJCC pathologic spread: Lymph nodes (pN)	☐ NX ☐ N0 ☐ N1	3203106	Using the patient's pathology/laboratory report, select the code for the pathologic N (nodal) as defined by the American Joint Committee on Cancer (AJCC).
41	AJCC pathologic spread: Distant metastases (pM)	☐ M0 ☐ M1b ☐ M1 ☐ M1c ☐ M1a ☐ MX	3045439	Using the patient's pathology/laboratory report, select the code for the pathologic M (metastasis) as defined by the American Joint Committee on Cancer (AJCC).
42	Tumor stage (pathological)	☐ Stage I ☐ Stage IIIA ☐ Stage II ☐ Stage IIIB ☐ Stage IIA ☐ Stage IIIC ☐ Stage IIB ☐ Stage IV ☐ Stage IIC ☐ Stage IVA ☐ Stage III ☐ Stage IVB	3065862	Using the patient's pathology/laboratory report, in conjunction with the patient's medical record, select the stage as defined by the American Joint Committee on Cancer (AJCC).
43	Histologic Grade Group: Gleason Grade Group	☐ Grade group 1 ☐ Grade group 2 ☐ Grade group 3 ☐ Grade group 4 ☐ Grade Group 5 ☐ Not applicable ☐ Cannot be assessed	5918370	Select the Gleason score group category.



Enrollment: Prostate

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
44	Gleason Score	☐ 2 ☐ 7 ☐ 3 ☐ 8 ☐ 4 ☐ 9 ☐ 5 ☐ 10 ☐ 6 ☐ Unknown	2433	Select the combined Gleason pattern score, which provides a reproducible description of the glandular architecture of prostate tissue depending primarily on the microscopic patterns of cancerous glands and cell morphology.
45	Primary Gleason grade	☐ 1 ☐ 4 ☐ 2 ☐ 5 ☐ 3 ☐ Unknown	5936800	Select the Primary Gleason score as defined by the most prevalent Gleason pattern in a prostate biopsy or prostatectomy specimen.
46	Secondary Gleason grade	☐ 1 ☐ 4 ☐ 2 ☐ 5 ☐ 3 ☐ Unknown	5936802	Select the Secondary Gleason score as defined by the second most prevalent Gleason pattern in a prostate biopsy or prostatectomy specimen.
47	Was a tertiary pattern identified?	☐ Yes ☐ No ☐ Unknown	6819525	Indicate whether a tertiary Gleason score was identified. ***Note: If a tertiary Gleason score was identified, proceed to Question 48, otherwise, skip to Question 49.***
48	What tertiary pattern was identified?	☐ Gleason pattern 4 ☐ Gleason pattern 5	6826926	Select the pattern of the Gleason Tertiary Grade.
49	Percentage Gleason Patterns 4 and 5 (applicable to Gleason score greater than 7)	_____%	6826927	Provide the numeric value for the percent of Gleason pattern 4 or 5 when the Gleason Score is greater than 7.
Prognostic/Predictive/Lifestyle Features for Primary Tumor Prognosis or Responsiveness to Treatment				
50	Lymphovascular invasion present?	☐ Yes ☐ No ☐ Indeterminate ☐ Unknown	64727	Indicate whether large vessel (vascular) invasion or small, thin-walled (lymphatic) invasion was detected in the primary tumor.
51	Perineural invasion present?	☐ Yes ☐ No ☐ Unknown	64181	Indicate whether perineural invasion or infiltration of tumor or cancer is present.
52	Number of positive lymph nodes	_____	89	Provide the number of lymph nodes with disease involvement.
53	Number of lymph nodes tested	_____	3	Provide the total number of lymph nodes tested for the presence of cancer cells.
54	Additional pathologic findings	☐ None identified ☐ High-grade prostatic intraepithelial neoplasia (PIN) ☐ Adenosis (Atypical adenomatous hyperplasia) ☐ Inflammation (specify type) ☐ Nodular prostatic hyperplasia ☐ Other (specify)	2431605	Select all significant pathologic findings present in addition to the invasive prostate carcinoma. ***Note: if inflammation was identified, proceed to Question 54a. If the pathologic finding is not listed, proceed to Question 54b, otherwise, skip to Question 55.***
54a	Specify inflammation type	_____	2431606	Indicate the predominant cell type or chronicity of inflammation in the prostate gland.
54b	Specify other additional pathologic findings	_____	6819520	If not included in previous list, specify all significant pathologic findings present in addition to the invasive prostate carcinoma.
55	Extraprostatic extension	☐ Not identified ☐ Cannot be determined ☐ Present, focal ☐ Present, nonfocal ☐ Unknown	6819521	Indicate the extraprostatic disease extension.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
56	Urinary bladder neck invasion	☐ Yes ☐ No ☐ Unknown	6819522	Indicate whether the urinary bladder neck has been invaded by tumor cells.
57	Seminal vesicle invasion	☐ Yes ☐ Unknown ☐ No	65074	Indicate whether invasion of the seminal vesicles by cancer is present.
58	Tumor margin	☐ Cannot be assessed ☐ Uninvolved by invasive carcinoma ☐ Involved by invasive carcinoma	6819523	Indicate the margin involvement by invasive carcinoma. ***Note: If the tumor margin is involved by invasive carcinoma, proceed to Question 58a, otherwise, skip to Question 59.***
58a	If tumor margin involved by invasive carcinoma, indicate the type	☐ Limited (≤3mm) ☐ Non-limited (>3mm)	6819524	Indicate the extent of a tumor border that is invading the adjacent tissue.
59	Treatment effect	☐ No known presurgical therapy ☐ Not identified ☐ Radiation therapy effect present ☐ Hormonal therapy effect present ☐ Other therapy effect(s) present (specify) ☐ Cannot be determined	6819618	Indicate the effect of treatment for prostate cancer. ***Note: If other therapy effect(s) are present, proceed to Question 59a, otherwise, skip to Question 60.***
59a	Specify other treatment effect	_____	6819619	Specify other therapy effect(s) present.
60	PSA value (ng/mL) at diagnosis	_____ng/mL	1806	Provide the patient's measured laboratory value of PSA (prostate specific antigen) in ng/mL at the time of prostate cancer diagnosis.
61	PSA value (ng/mL) at progression	_____ng/mL	1817	Provide the patient's measured laboratory value of PSA (prostate specific antigen) in ng/mL at the time of prostate cancer progression.
62	Intraductal carcinoma (IDC)	☐ Not identified ☐ Present ☐ Cannot be determined	6819526	Indicate whether intraductal prostate carcinoma is present.
63	Residual tumor/margins	☐ RX ☐ R1 ☐ R0 ☐ R2	2608702	Indicate the status of the tissue margin following surgical resection.
64	Was the patient ever treated for benign prostatic hyperplasia (BPH)?	☐ Yes ☐ No ☐ Unknown	6819528	Indicate whether the patient was treated for benign prostatic hyperplasia. ***Note: If the patient was treated for BPH, proceed to Question 65, otherwise, skip to Question 66.***
65	If the patient was treated for BPH, which treatments were administered?	☐ Finasteride ☐ Dutasteride ☐ TURP ☐ Unknown ☐ Other (specify)	6819529	Indicate the kind of treatment administered for benign prostatic hyperplasia. ***Note: If the BPH treatment is not listed, proceed to Question 65a, otherwise, skip to Question 66.***
65a	Specify other BPH treatment administered	_____	6819530	Specify another kind of treatment for benign prostatic hyperplasia not previously listed.
66	Was imaging (beyond ultrasound) used in diagnosis of the primary tumor?	☐ Yes ☐ No ☐ Unknown	6819569	Indicate whether imaging (beyond ultrasound) was used in diagnosis of the primary tumor. ***Note: If imaging beyond ultrasound was used, proceed to Question 67, otherwise, skip to Question 69.***
67	Indicate the imaging method(s) used in diagnosis of the primary tumor	☐ MRI ☐ PET (specify) ☐ CT scan ☐ 99mTc bone scintiscanning ☐ Other (specify)	6819588	Indicate the kind of imaging used to diagnose the primary tumor. ***Note: If PET scan was used, proceed to Question 68. If the imaging method is not listed, proceed to Question 67a, otherwise, skip to Question 69.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
67a	Other imaging method(s) used in diagnosis of the primary tumor	_____	6819607	If not included in the previous list, specify the kind of imaging used to diagnose the primary tumor.
68	For PET scans, indicate the tracer used	☐ Axumin ☐ PSMA ☐ Choline ☐ Sodium fluoride ☐ Acetate ☐ Other (specify)	6819581	Indicate the kind of tracer used in Positron Emission Tomography (PET) imaging. ***Note: If the tracer is not listed, proceed to Question 68a, otherwise, skip to Question 69.***
68a	Other PET scan tracer used	_____	6819582	If not included in the previous list, specify the kind of tracer used in Positron Emission Tomography (PET) imaging.
69	Was the primary tumor identified in subsequent imaging evaluation?	☐ Yes ☐ No ☐ Unknown	6819575	Indicate whether the primary tumor was identified in a subsequent imaging evaluation.
70	Indicate the imaging method(s) in subsequent evaluation that identified the primary tumor	☐ MRI ☐ PET (specify) ☐ CT scan ☐ 99mTc bone scintiscanning ☐ Other (specify)	6819576	Indicate the kind of subsequent imaging the identified the primary tumor. ***Note: If PET scan was used, proceed to Question 71. If the imaging method is not listed, proceed to Question 70a, otherwise, skip to Question 72.***
70a	Specify the imaging method(s) in subsequent evaluation that identified the primary tumor	_____	6832443	If not included in the previous list, specify the kind of subsequent imaging that identified the primary tumor.
71	For PET scans, indicate the tracer used	☐ Axumin ☐ PSMA ☐ Choline ☐ Sodium fluoride ☐ Acetate ☐ Other (specify)	6819581	Indicate the kind of tracer used in Positron Emission Tomography (PET) imaging. ***Note: If the tracer is not listed, proceed to Question 71a, otherwise, skip to Question 72.***
71a	Other PET scan tracer used	_____	6819582	If not included in the previous list, specify the kind of tracer used in Positron Emission Tomography (PET) imaging.
72	Was the presence of circulating tumor cells (CTCs) tested?	☐ Yes ☐ No ☐ Unknown	6829555	Indicate whether a test for circulating tumor cells was performed. ***Note: If CTC presence was examined, proceed to Question 73, otherwise, skip to Question 78.***
73	Circulating tumor cell test result	☐ Absent ☐ Present	6819986	Indicate whether circulating tumor cells are present or absent. ***Note: If CTCs are present, proceed to Question 74, otherwise, skip to Question 78.***
74	Number of circulating tumor cells (CTCs)	_____	3145287	Provide the numeric count of circulating tumor cells found in a specimen of the patient's peripheral blood.
75	Blood sample volume used to analyze number of CTC cells	_____	3219439	Provide the volume of the blood sample used to detect circulating tumor cells.
76	Was AR-V7 tested in circulating tumor cells?	☐ Yes ☐ Unknown ☐ No	6821457	Indicate whether or not AR-V7 was tested in circulating tumor cells.
77	Circulating tumor cell AR-V7 result	☐ Present ☐ Absent	6821463	Indicate the result of the test for AR-V7 in circulating tumor cells.
78	Genomic test performed?	☐ Yes ☐ No ☐ Unknown	6069581	Indicate whether a genomic biomarker test was performed. ***Note: If genomic testing was performed, proceed to Question 79, otherwise, skip to Question 85.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
79	What genomic test was performed?	☐ Decipher ☐ Oncotype Dx Prostate ☐ Prolaris ☐ ProMark ☐ Other (specify)	6069582	Select the genomic biomarker test that was performed. ***Note: If Decipher was used, proceed to Question 81. If Oncotype Dx Prostate was used, proceed to Question 82. If Prolaris was used, proceed to Question 83. If ProMark was used, proceed to Question 84. If the genomic test is not listed, proceed to Question 79a, otherwise, skip to Question 85.***
79a	Other genomic test performed	_____	6069583	If not included in the previous list, provide the genomic biomarker test that was performed. ***Note: If an other genomic test was used, proceed to Question 80.***
80	If other genomic test was performed, provide the risk group	_____	6070422	Specify the risk group for prostate cancer as determined by assessment of an other genomic test.
81	What is the patient's Decipher score?	_____	6819987	Provide the numeric score for the Decipher prostate cancer test.
82	What is the patient's risk group according to the Oncotype Genomic Prostate Score?	☐ Very low ☐ Low ☐ Favorable intermediate ☐ Intermediate ☐ High	6819988	Indicate the risk group based on the Oncotype DX Genomic Prostate test score.
83	What is the patient's Prolaris molecular score?	_____	6819989	Provide the numeric score for the Prolaris prostate cancer test.
84	What is the patient's ProMark risk score?	_____	6820003	Provide the numeric score for the ProMark prostate cancer test.
85	Was mutational analysis performed on any of the following genes? (select all that apply)	☐ BRCA1 ☐ BRCA2 ☐ ATM ☐ CHEK2 ☐ HOXB1 ☐ FANCA ☐ PALB2 ☐ Unknown	6820040	Select all genes for which mutational analysis was performed.
86	Was a mutation in BRCA1 identified?	☐ Yes ☐ No ☐ Unknown	2437532	Indicate whether a mutation in BRCA1 was identified. ***Note: If a mutation was identified, proceed to Question 86a, otherwise, skip to Question 87.***
86a	Specify BRCA1 mutation	_____	6690688	Specify the BRCA1 variant identified as the result of mutational analysis.
86b	Tissue submitted for mutational analysis	☐ Blood ☐ Normal tissue ☐ Tumor ☐ Other (specify)	6820004	Indicate the kind of tissue submitted for mutational analysis. ***Note: If the tissue is not listed, proceed to Question 86c, otherwise, skip to Question 87.***
86c	Other tissue submitted for mutational analysis	_____	6820011	If not included in the previous list, provide the kind of tissue submitted for mutational analysis.
87	Was a mutation in BRCA2 identified?	☐ Yes ☐ No ☐ Unknown	2437543	Indicate whether a mutation in BRCA2 was identified. ***Note: If a mutation was identified, proceed to Question 87a, otherwise, skip to Question 88.***
87a	Specify BRCA2 mutation	_____	6690693	Specify the BRCA2 variant identified as the result of mutational analysis.
87b	Tissue submitted for mutational analysis	☐ Blood ☐ Normal tissue ☐ Tumor ☐ Other (specify)	6820004	Indicate the kind of tissue submitted for mutational analysis. ***Note: If the tissue is not listed, proceed to Question 87c, otherwise, skip to Question 88.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
87c	Other tissue submitted for mutational analysis	_____	6820011	If not included in the previous list, provide the kind of tissue submitted for mutational analysis.
88	Was a mutation in HOXB1 identified?	☐ Yes ☐ No ☐ Unknown	6840947	Indicate whether a mutation in HOXB1 was identified. ***Note: If a mutation was identified, proceed to Question 88a, otherwise, skip to Question 89.***
88a	Specify HOXB1 mutation	_____	6840948	Specify the HOXB1 variant identified as the result of mutational analysis.
88b	Tissue submitted for mutational analysis	☐ Blood ☐ Tumor ☐ Normal tissue ☐ Other (specify)	6820004	Indicate the kind of tissue submitted for mutational analysis. ***Note: If the tissue is not listed, proceed to Question 88c, otherwise, skip to Question 89.***
88c	Other tissue submitted for mutational analysis	_____	6820011	If not included in the previous list, provide the kind of tissue submitted for mutational analysis.
89	Was a mutation in ATM identified?	☐ Yes ☐ No ☐ Unknown	6005210	Indicate whether a mutation in ATM was identified. ***Note: If a mutation was identified, proceed to Question 89a, otherwise, skip to Question 90.***
89a	Specify ATM mutation	_____	6820015	Specify the ATM variant identified as the result of mutational analysis.
89b	Tissue submitted for mutational analysis	☐ Blood ☐ Tumor ☐ Normal tissue ☐ Other (specify)	6820004	Indicate the kind of tissue submitted for mutational analysis. ***Note: If the tissue is not listed, proceed to Question 89c, otherwise, skip to Question 90.***
89c	Other tissue submitted for mutational analysis	_____	6820011	If not included in the previous list, provide the kind of tissue submitted for mutational analysis.
90	Was a mutation in PALB2 identified?	☐ Yes ☐ No ☐ Unknown	6820021	Indicate whether a mutation in PALB2 was identified. ***Note: If a mutation was identified, proceed to Question 90a, otherwise, skip to Question 91.***
90a	Specify PALB2 mutation	_____	6820016	Specify the PALB2 variant identified as the result of mutational analysis.
90b	Tissue submitted for mutational analysis	☐ Blood ☐ Tumor ☐ Normal tissue ☐ Other (specify)	6820004	Indicate the kind of tissue submitted for mutational analysis. ***Note: If the tissue is not listed, proceed to Question 90c, otherwise, skip to Question 91.***
90c	Other tissue submitted for mutational analysis	_____	6820011	If not included in the previous list, provide the kind of tissue submitted for mutational analysis.
91	Was a mutation in FANCA identified?	☐ Yes ☐ No ☐ Unknown	6820022	Indicate whether a mutation in FANCA was identified. ***Note: If a mutation was identified, proceed to Question 91a, otherwise, skip to Question 92.***
91a	Specify FANCA mutation	_____	6820017	Specify the FANCA variant identified as the result of mutational analysis.
91b	Tissue submitted for mutational analysis	☐ Blood ☐ Tumor ☐ Normal tissue ☐ Other (specify)	6820004	Indicate the kind of tissue submitted for mutational analysis. ***Note: If the tissue is not listed, proceed to Question 91c, otherwise, skip to Question 92.***
91c	Other tissue submitted for mutational analysis	_____	6820011	If not included in the previous list, provide the kind of tissue submitted for mutational analysis.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
92	Was a mutation in CHEK2 identified?	☐ Yes ☐ No ☐ Unknown	6005214	Indicate whether a mutation in CHEK2 was identified. ***Note: If a mutation was identified, proceed to Question 92a, otherwise, skip to Question 93.***
92a	Specify CHEK2 mutation	_____	6832296	Specify the type of CHEK2 variant identified as the result of mutational analysis.
92b	Tissue submitted for mutational analysis	☐ Blood ☐ Tumor ☐ Normal tissue ☐ Other (specify)	6820004	Indicate the kind of tissue submitted for mutational analysis. ***Note: If the tissue is not listed, proceed to Question 92c, otherwise, skip to Question 93.***
92c	Other tissue submitted for mutational analysis	_____	6820011	If not included in the previous list, provide the kind of tissue submitted for mutational analysis.
93	Was AR-V7 RNA ISH (RISH) performed?	☐ Yes ☐ No ☐ Unknown	6821464	Indicate whether or not in situ hybridization for AR-V7 RNA (RISH) was performed. ***Note: If AR-V7 RNA ISH was performed, proceed to Question 94, otherwise, skip to Question 95.***
94	AR-V7 RNA ISH result	☐ Positive ☐ Negative ☐ Equivocal	6821465	Indicate the result of AR-V7 RNA testing by in situ hybridization.
95	Was AR-V7 RT-PCR performed?	☐ Yes ☐ No ☐ Unknown	6821476	Indicate whether AR-V7 messenger RNA Reverse Transcriptase-Polymerase Chain Reaction was performed. ***Note: If AR-V7 RT-PCR was performed, proceed to Question 96, otherwise, skip to Question 97.***
96	AR-V7 RT-PCR result	☐ Positive ☐ Negative ☐ Equivocal	6821477	Indicate the result of the AR-V7 messenger RNA Reverse Transcriptase-Polymerase Chain Reaction test.
97	Was IHC performed for any of the following proteins? (select all that apply)	☐ AR ☐ PMS2 ☐ AR-V7 ☐ MSH6 ☐ MLH1 ☐ PTEN ☐ MSH2 ☐ Unknown	6820057	Select all the proteins for which immunohistochemistry (IHC) was performed.
98	AR expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6788031	Indicate the status of the Androgen Receptor protein expression using immunohistochemistry.
99	AR-V7 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6821495	Indicate the status of the AR-V7 protein expression using immunohistochemistry.
100	MLH1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063668	Indicate the status of the MLH1 protein expression using immunohistochemistry.
101	MSH2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063669	Indicate the status of the MSH2 protein expression using immunohistochemistry.
102	PMS2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063670	Indicate the status of the PMS2 protein expression using immunohistochemistry.
103	MSH6 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063671	Indicate the status of the MSH6 protein expression using immunohistochemistry.
104	PTEN expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063672	Indicate the status of the PTEN protein expression using immunohistochemistry.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
105	MLH1 promoter methylation status	☐ Present ☐ Absent ☐ Indeterminate ☐ Not assessed	6033150	Indicate the methylation status of the MLH1 promoter.
106	MMR status	☐ Evidence of MMR mutation by sequencing ☐ Evidence of MMR protein loss by IHC ☐ MMR loss evidence hypermutation phenotype (>10 mutations/Mb) ☐ No evidence of MMR alteration ☐ Not performed	6002208	Indicate the patient's Mismatch Repair (MMR) gene mutation status.
Primary Tumor Sample Information				
107	Are you submitting a primary tumor tissue sample for this case?	☐ Yes ☐ No		***If yes, proceed to question 108. If submitting a metastatic/recurrent tumor biospecimen, proceed to Question 142.***
108	Primary tumor biospecimen ordinal	_____	6584265	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number should be "1".***
109	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
110	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
111	Sample represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this primary tumor specimen represent the PRIMARY DIAGNOSIS for this Case ID3? ***Note: If no, proceed to Question 112, otherwise, skip to Question 113.***
112	Specify the ICD-10 code	_____	3226287	Provide the ICD-10 code for the primary tumor used to generate the model submitted to HCMI.
113	Tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the tumor tissue sample collected for molecular characterization.
114	Other anatomic site from which the tumor was obtained	☐ Prostate ☐ Other (specify)	4214629	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI. ***Note: If the tissue or organ not listed, proceed to Question 114a. Otherwise, skip to Question 115.***
114a	Other anatomic site from which the tumor was obtained: Lip and oral cavity	_____	5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.
115	Method of cancer sample procurement	☐ Needle biopsy ☐ TURP including all forms of enucleation ☐ Subtotal prostatectomy ☐ Radical prostatectomy ☐ Other (specify)	3103514	Provide the procedure performed to obtain the primary tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 115a, otherwise, skip to Question 116. If TURP is selected, proceed to Question 116, otherwise, skip to Question 122.***
115a	Specify the other method of tumor sample procurement	_____	2006730	Specify the procedure performed to obtain the primary tumor tissue, if not included in the previous list.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
116	For TURP specimens, number of positive chips	_____	2431688	Provide the number of chips involved by invasive prostate carcinoma, in a transurethral resection specimen.
117	For TURP specimens, number of total chips	_____	2431624	Provide the total number of chips in a specimen of prostate removed by transurethral resection.
118	For TURP specimens, estimated percentage of prostatic tissue involved by tumor	_____%	2431904	Provide the percentage of prostatic tissue which is involved by invasive prostate carcinoma, in a transurethral resection specimen.
119	For enucleation specimens, estimated percentage of prostatic tissue involved by tumor	_____%	6831339	Provide the percentage of prostatic tissue which is involved by tumor.
120	For enucleation specimens, tumor size (dominant nodule, if present)	_____mm	6831608	Provide the numeric value in mm for the size of the dominant (if present) tumor nodule.
121	For enucleation specimens, additional dimensions (millimeters)	_____mm	6831609	Provide the numeric value in mm for an additional dimension of the tumor.
122	Number of days from index date to date of tumor sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the tumor tissue submitted for HCMI.
123	Tumor tissue type	☐ Primary ☐ Additional Primary ☐ NOS	3288124	Provide the primary tumor tissue type for this sample.
Primary Tumor Model Information				
124	Primary model biospecimen ordinal	_____	6594596	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number is expected to be "1".***
125	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
126	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
127	Model represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this model represent the primary diagnosis for this Case ID3?
128	Model's primary tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the PRIMARY TUMOR TISSUE from which this model is derived.
129	Model's primary tumor biospecimen ordinal	_____	6584265	Enter the biospecimen ordinal of the PRIMARY TUMOR TISSUE from which this model is derived.
Treatment Information				
130	History of neoadjuvant treatment	☐ No ☐ Yes; radiation prior to resection ☐ Yes; pharmaceutical treatment prior to resection ☐ Yes; both radiation and pharmaceutical treatment prior to resection ☐ Unknown	3382737	Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment. ***Note: Pharmaceutical therapy is addressed in Questions 131-139. Radiation therapy is addressed in Questions 140-141.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
131	Neoadjuvant chemotherapy type	☐ Cytotoxic chemotherapy ☐ Hormonal ☐ Immunotherapy (cellular and immune checkpoint) ☐ Targeted therapy (small molecule inhibitors and targeted antibodies) ☐ Not applicable	5832928	Select all neoadjuvant chemotherapy types that were administered to the patient. ***Note: Cytotoxic chemotherapy is addressed in Questions 132-133. Hormone therapy is addressed in Questions 134-135. Immunotherapy is addressed in Questions 136-137. Targeted therapy is addressed in Questions 138-139.***
132	Neoadjuvant chemotherapeutic regimen	☐ Etoposide with cisplatin ☐ Etoposide with carboplatin ☐ Docetaxel ☐ Cabazitaxel ☐ Prednisone ☐ Decadron (dexamethasone) ☐ Androgen deprivation therapy (ADT) ☐ Other (specify)	2853313	Select all chemotherapeutics used for neoadjuvant therapy. ***Note: If neoadjuvant chemotherapy was not given, skip to Question 134. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 132a, otherwise, skip to Question 133.***
132a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapies administered.
133	Days to neoadjuvant chemotherapy treatment from index date	_____	5102411	Provide the number of days from index date to the date of treatment with neoadjuvant chemotherapy.
134	Hormone therapy	☐ Leuprolide ☐ Goserelin ☐ Triptorelin ☐ Histrelin ☐ Degarelix ☐ Orteranel ☐ Abiraterone ☐ Flutamide ☐ Bicalutamide ☐ Nilutamide ☐ Enzalutamide ☐ Apalutamide ☐ Darolutamide ☐ Itraconazole ☐ Ketoconazole ☐ Other (specify)	6819511	Select the hormone therapy administered to the patient. ***Note: If hormone therapy was not administered, skip to Question 136. If the hormone therapy is not listed, proceed to Question 134a, otherwise, skip to Question 135.***
134a	Other hormone therapy	_____	2405358	If the hormone therapy is not included in the provided list, specify hormone therapy.
135	Days to hormone therapy treatment from index date	_____	5102411	Provide the number of days from index date to the date of treatment with hormone therapy.
136	Immunotherapy	☐ Provenge ☐ Pembrolizumab ☐ Nivolumab ☐ Ipilimumab ☐ Other (specify)	6819519	Select the immunotherapy administered to the patient. ***Note: If immunotherapy was not administered, skip to Question 138. If the immunotherapy is not listed, proceed to Question 136a, otherwise, skip to Question 137.***
136a	Specify other immunotherapy	_____	2953828	Provide the name of the immunotherapy administered to the patient.
137	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
138	Targeted Therapy	☐ Bevacizumab ☐ AZD5363 ☐ MK2206 ☐ Olaparib ☐ Rucaparib ☐ Niraparib ☐ Other (specify)	6819512	Select the targeted therapy administered to the patient. ***Note: If targeted therapy was not administered, skip to Question 140. If the targeted therapy regimen is not listed, proceed to Question 138a, otherwise, skip to Question 139.***
138a	Specify targeted therapy	_____	4308476	Provide the name of the targeted therapy administered to the patient.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
139	Days to targeted therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with targeted therapy.
140	Radiation therapy administered type	☐ 2D conventional ☐ 3D conformal ☐ Brachytherapy HDR ☐ Brachytherapy LDR ☐ IMRT ☐ Proton Beam ☐ Stereotactic Body RT ☐ Stereotactic Radiosurgery ☐ WBRT ☐ Other (specify) ☐ Unspecified ☐ Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. ***Note: If radiation therapy was not administered, proceed to Question 142. If the radiation therapy is not listed, proceed to Question 140a, otherwise, skip to Question 141.***
140a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
141	Days to radiation treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with radiation therapy.
Metastatic/Recurrent Tumor Biospecimen Information				
142	Are you submitting a metastatic/recurrent tumor tissue sample?	☐ Yes ☐ No		Indicate whether a metastatic/recurrent tumor biospecimen was collected for this ID3 case. ***Note: If yes, proceed to Question 143. If submitting an OTHER tissue sample, proceed to Question 234.***
143	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1", the second should be number "2", etc.***
144	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
145	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
146	Metastatic/recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
147	Number of days from index date to date of diagnosis of metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic/recurrent disease.
148	Method of metastatic/ recurrent cancer sample procurement	☐ Core needle biopsy ☐ Fine needle aspirate ☐ TURP including all forms of enucleation ☐ Salvaged radical prostatectomy ☐ Salvaged lymph node dissection ☐ Metastasectomy ☐ Other Method (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 148a, otherwise, skip to Question 149.***
148a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.



Enrollment: Prostate

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
149	For TURP specimens, number of positive chips	_____	2431688	Provide the number of chips involved by invasive prostate carcinoma, in a transurethral resection specimen.
150	For TURP specimens, number of total chips	_____	2431624	Provide the total number of chips in a specimen of prostate removed by transurethral resection.
151	For TURP specimens, estimated percentage of prostatic tissue involved by tumor	_____%	2431904	Provide the percentage of prostatic tissue which is involved by invasive prostate carcinoma, in a transurethral resection specimen.
152	For enucleation specimens, estimated percentage of prostatic tissue involved by tumor	_____%	6831339	Provide the percentage of prostatic tissue which is involved by tumor.
153	For enucleation specimens, tumor size (dominant nodule, if present)	_____mm	6831608	Provide the numeric value in mm for the size of the dominant (if present) tumor nodule.
154	For enucleation specimens, additional dimensions (millimeters)	_____mm	6831609	Provide the numeric value in mm for an additional dimension of the tumor.
155	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
156	Metastatic/recurrent site	☐ Prostate ☐ Lymph node(s) ☐ Bone ☐ Lung ☐ Liver ☐ Brain ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 156a, otherwise, skip to Question 157.***
156a	Other metastatic/ recurrent site	_____	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
157	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
158	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
159	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
160	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
161	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.



Enrollment: Prostate

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
162	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
163	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
164	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
Prognostic/Predictive/Lifestyle Features for Metastatic/Recurrent Tumor Prognosis or Responsiveness to Treatment				
165	Lymphovascular invasion present?	☐ Yes ☐ No ☐ Indeterminate ☐ Unknown	64727	Indicate whether large vessel (vascular) invasion or small, thin-walled (lymphatic) invasion was detected in the primary tumor.
166	Perineural invasion present?	☐ Yes ☐ No ☐ Unknown	64181	Indicate whether perineural invasion or infiltration of tumor or cancer is present.
167	Number of positive lymph nodes	_____	89	Provide the number of lymph nodes with disease involvement.
168	Number of lymph nodes tested	_____	3	Provide the total number of lymph nodes tested for the presence of cancer cells.
169	PSA value (ng/mL) at progression	_____ng/mL	1817	Provide the patient's measured laboratory value of PSA (prostate specific antigen) in ng/mL at the time when progression or biochemical failure is reported.
170	For metastatic tumor biopsies, was the site positive by imaging prior to biopsy?	☐ Yes ☐ No ☐ Unknown	6819981	Indicate whether the metastatic tumor site was positive by imaging prior to biopsy. ***Note: If imaging identified the metastatic lesion, proceed to Question 171, otherwise, skip to Question 173.***
171	If yes, indicate the imaging method used to identify the metastatic site biopsied	☐ MRI ☐ PET (specify) ☐ CT scan ☐ 99mTc bone scintiscanning ☐ Other (specify)	6819586	Indicate the imaging method(s) used to identify the metastatic site biopsied. ***Note: If the imaging method is not listed, proceed to Question 171a, otherwise, skip to Question 173. If PET scan was used, proceed to Question 172, otherwise, skip to Question 173.***
171a	Other imaging method(s) used to identify the metastatic site biopsied	_____	6819611	If not included in the previous list, specify the kind of subsequent imaging that identified the metastatic site biopsied.
172	For PET scans, indicate the tracer used	☐ Axumin ☐ Choline ☐ Acetate ☐ PSMA ☐ Sodium fluoride ☐ Other (specify)	6819581	Indicate the kind of tracer used in Positron Emission Tomography (PET) imaging. ***Note: If the tracer is not listed, proceed to Question 172a, otherwise, skip to Question 173.***
172a	Other PET scan tracer used	_____	6819582	If not included in the previous list, specify the kind of tracer used in Positron Emission Tomography (PET) imaging.



Enrollment: Prostate

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
173	Was the presence of circulating tumor cells (CTCs) tested?	☐ Yes ☐ No ☐ Unknown	6829555	Indicate whether a test for circulating tumor cells was performed. ***Note: If CTCs are present, proceed to Question 174, otherwise, skip to Question 179.***
174	Circulating tumor cell test result	☐ Present ☐ Absent	6819986	Indicate whether circulating tumor cells are present or absent. ***Note: If CTCs were present, proceed to Question 175, otherwise, skip to Question 179.***
175	Number of circulating tumor cells (CTCs)	_____	3145287	Provide the numeric count of circulating tumor cells found in a specimen of the patient's peripheral blood.
176	Blood sample volume used to analyze number of CTC cells	_____	3219439	Provide the volume of the blood sample used to detect circulating tumor cells.
177	Was AR-V7 tested in circulating tumor cells?	☐ Yes ☐ No ☐ Unknown	6821457	Indicate whether or not AR-V7 was tested in circulating tumor cells. ***Note: If AR-V7 was tested in CTCs, proceed to Question 178, otherwise, skip to Question 179.***
178	Circulating tumor cell AR-V7 result	☐ Present ☐ Absent	6821463	Indicate the result of the test for AR-V7 in circulating tumor cells.
179	Was mutational analysis performed on any of the following genes? (select all that apply)	☐ BRCA1 ☐ CHEK2 ☐ PALB2 ☐ BRCA2 ☐ HOXB1 ☐ Unknown ☐ ATM ☐ FANCA	6820040	Select all genes for which mutational analysis was performed.
180	Was a mutation in BRCA1 identified?	☐ Yes ☐ No ☐ Unknown	2437532	Indicate whether a mutation in BRCA1 was identified. ***Note: If a mutation was identified, proceed to Question 180a, otherwise, skip to Question 181.***
180a	Specify BRCA1 mutation	_____	6690688	Specify the BRCA1 variant identified as the result of mutational analysis.
180b	Tissue submitted for mutational analysis	☐ Blood ☐ Tumor ☐ Normal tissue ☐ Other (specify)	6820004	Indicate the kind of tissue submitted for mutational analysis. ***Note: If the tissue is not listed, proceed to Question 180c, otherwise, skip to Question 181.***
180c	Other tissue submitted for mutational analysis	_____	6820011	If not included in the previous list, provide the kind of tissue submitted for mutational analysis.
181	Was a mutation in BRCA2 identified?	☐ Yes ☐ No ☐ Unknown	2437543	Indicate whether a mutation in BRCA2 was identified. ***Note: If a mutation was identified, proceed to Question 181a, otherwise, skip to Question 182.***
181a	Specify BRCA2 mutation	_____	6690693	Specify the BRCA2 variant identified as the result of mutational analysis.
181b	Tissue submitted for mutational analysis	☐ Blood ☐ Tumor ☐ Normal tissue ☐ Other (specify)	6820004	Indicate the kind of tissue submitted for mutational analysis. ***Note: If the tissue is not listed, proceed to Question 181c, otherwise, skip to Question 182.***
181c	Other tissue submitted for mutational analysis	_____	6820011	If not included in the previous list, provide the kind of tissue submitted for mutational analysis.
182	Was a mutation in HOXB1 identified?	☐ Yes ☐ No ☐ Unknown	6840947	Indicate whether a mutation in HOXB1 was identified. ***Note: If a mutation was identified, proceed to Question 182a, otherwise, skip to Question 183.***



Enrollment: Prostate

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
182a	Specify HOXB1 mutation	_____	6840948	Specify the HOXB1 variant identified as the result of mutational analysis.
182b	Tissue submitted for mutational analysis	☐ Blood ☐ Normal tissue ☐ Tumor ☐ Other (specify)	6820004	Indicate the kind of tissue submitted for mutational analysis. ***Note: If the tissue is not listed, proceed to Question 182c, otherwise, skip to Question 183.***
182c	Other tissue submitted for mutational analysis	_____	6820011	If not included in the previous list, provide the kind of tissue submitted for mutational analysis.
183	Was a mutation in ATM identified?	☐ Yes ☐ No ☐ Unknown	6005210	Indicate whether a mutation in ATM was identified. ***Note: If a mutation was identified, proceed to Question 183a, otherwise, skip to Question 184.***
183a	Specify ATM mutation	_____	6820015	Specify the ATM variant identified as the result of mutational analysis.
183b	Tissue submitted for mutational analysis	☐ Blood ☐ Normal tissue ☐ Tumor ☐ Other (specify)	6820004	Indicate the kind of tissue submitted for mutational analysis. ***Note: If the tissue is not listed, proceed to Question 183c, otherwise, skip to Question 184.***
183c	Other tissue submitted for mutational analysis	_____	6820011	If not included in the previous list, provide the kind of tissue submitted for mutational analysis.
184	Was a mutation in PALB2 identified?	☐ Yes ☐ No ☐ Unknown	6820021	Indicate whether a mutation in PALB2 was identified. ***Note: If a mutation was identified, proceed to Question 184a, otherwise, skip to Question 185.***
184a	Specify PALB2 mutation	_____	6820016	Specify the PALB2 variant identified as the result of mutational analysis.
184b	Tissue submitted for mutational analysis	☐ Blood ☐ Normal tissue ☐ Tumor ☐ Other (specify)	6820004	Indicate the kind of tissue submitted for mutational analysis. ***Note: If the tissue is not listed, proceed to Question 184c, otherwise, skip to Question 185.***
184c	Other tissue submitted for mutational analysis	_____	6820011	If not included in the previous list, provide the kind of tissue submitted for mutational analysis.
185	Was a mutation in FANCA identified?	☐ Yes ☐ No ☐ Unknown	6820022	Indicate whether a mutation in FANCA was identified. ***Note: If a mutation was identified, proceed to Question 185a, otherwise, skip to Question 186.***
185a	Specify FANCA mutation	_____	6820017	Specify the FANCA variant identified as the result of mutational analysis.
185b	Tissue submitted for mutational analysis	☐ Blood ☐ Normal tissue ☐ Tumor ☐ Other (specify)	6820004	Indicate the kind of tissue submitted for mutational analysis. ***Note: If the tissue is not listed, proceed to Question 185c, otherwise, skip to Question 186.***
185c	Other tissue submitted for mutational analysis	_____	6820011	If not included in the previous list, provide the kind of tissue submitted for mutational analysis.
186	Was a mutation in CHEK2 identified?	☐ Yes ☐ No ☐ Unknown	6005214	Indicate whether a mutation in CHEK2 was identified. ***Note: If a mutation was identified, proceed to Question 186a, otherwise, skip to Question 187.***



Enrollment: Prostate

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
186a	Specify CHEK2 mutation	_____	6832296	Specify the type of CHEK2 variant identified as the result of mutational analysis.
186b	Tissue submitted for mutational analysis	☐ Blood ☐ Normal tissue ☐ Tumor ☐ Other (specify)	6820004	Indicate the kind of tissue submitted for mutational analysis. ***Note: If the tissue is not listed, proceed to Question 186c, otherwise, skip to Question 187.***
186c	Other tissue submitted for mutational analysis	_____	6820011	If not included in the previous list, provide the kind of tissue submitted for mutational analysis.
187	Was AR-V7 RNA ISH (RISH) performed?	☐ Yes ☐ No ☐ Unknown	6821464	Indicate whether or not in situ hybridization for AR-V7 RNA (RISH) was performed. ***Note: If AR-V7 RNA ISH was performed, proceed to Question 188, otherwise, skip to Question 189.***
188	AR-V7 RNA ISH result	☐ Positive ☐ Negative ☐ Equivocal	6821465	Indicate the result of AR-V7 RNA testing by in situ hybridization.
189	Was AR-V7 RT-PCR performed?	☐ Yes ☐ No ☐ Unknown	6821476	Indicate whether AR-V7 messenger RNA Reverse Transcriptase-Polymerase Chain Reaction was performed. ***Note: If AR-V7 RT-PCR was performed, proceed to Question 190, otherwise, skip to Question 191.***
190	AR-V7 RT-PCR result	☐ Positive ☐ Negative ☐ Equivocal	6821477	Indicate the result of the AR-V7 messenger RNA Reverse Transcriptase-Polymerase Chain Reaction test.
191	Was IHC performed for any of the following proteins? (select all that apply)	☐ AR ☐ AR-V7 ☐ MLH1 ☐ MSH2 ☐ PMS2 ☐ MSH6 ☐ PTEN ☐ Unknown	6820057	Select all the proteins for which immunohistochemistry (IHC) was performed.
192	AR expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6788031	Indicate the status of the Androgen Receptor protein expression using immunohistochemistry.
193	AR-V7 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6821495	Indicate the status of the AR-V7 protein expression using immunohistochemistry.
194	MLH1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063668	Indicate the status of the MLH1 protein expression using immunohistochemistry.
195	MSH2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063669	Indicate the status of the MSH2 protein expression using immunohistochemistry.
196	PMS2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063670	Indicate the status of the PMS2 protein expression using immunohistochemistry.
197	MSH6 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063671	Indicate the status of the MSH6 protein expression using immunohistochemistry.
198	PTEN expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063672	Indicate the status of the PTEN protein expression using immunohistochemistry.
199	MLH1 promoter methylation status	☐ Present ☐ Absent ☐ Indeterminate ☐ Not assessed	6033150	Indicate the methylation status of the MLH1 promoter.



Enrollment: Prostate

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
200	MMR status	☐ Evidence of MMR mutation by sequencing ☐ Evidence of MMR protein loss by IHC ☐ MMR loss evidence hypermutation phenotype (>10 mutations/Mb) ☐ No evidence of MMR alteration ☐ Not performed	6002208	Indicate the patient's Mismatch Repair (MMR) gene mutation status.
Additional Metastatic/Recurrent Tumor Biospecimen Information (if applicable)				
201	Are you submitting an additional metastatic/ recurrent tumor tissue sample?	☐ Yes ☐ No		A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen. ***Note: If yes, proceed to Question 202, otherwise, skip to Question 224.***
202	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. The first biospecimen should be number "1," the second should be number "2," etc.
203	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
204	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
205	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
206	Number of days from index date to date of diagnosis of additional metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of additional metastatic/recurrent disease.
207	Method of metastatic/ recurrent cancer sample procurement	☐ Core needle biopsy ☐ Fine needle aspirate ☐ TURP including all forms of enucleation ☐ Salvaged radical prostatectomy ☐ Salvaged lymph node dissection ☐ Metastasectomy ☐ Other Method (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 207a, otherwise, skip to Question 208. For TURP samples, proceed to Question 208, otherwise, skip to Question 214.***
207a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
208	For TURP specimens, number of positive chips	_____	2431688	Provide the number of chips involved by invasive prostate carcinoma, in a transurethral resection specimen.
209	For TURP specimens, number of total chips	_____	2431624	Provide the total number of chips in a specimen of prostate removed by transurethral resection.



Enrollment: Prostate

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
210	For TURP specimens, estimated percentage of prostatic tissue involved by tumor	_____%	2431904	Provide the percentage of prostatic tissue which is involved by invasive prostate carcinoma, in a transurethral resection specimen.
211	For enucleation specimens, estimated percentage of prostatic tissue involved by tumor	_____%	6831339	Provide the percentage of prostatic tissue which is involved by tumor.
212	For enucleation specimens, tumor size (dominant nodule, if present)	_____mm	6831608	Provide the numeric value in mm for the size of the dominant (if present) tumor nodule.
213	For enucleation specimens, additional dimensions (millimeters)	_____mm	6831609	Provide the numeric value in mm for an additional dimension of the tumor.
214	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
215	Metastatic/ recurrent site	☐ Prostate ☐ Lymph node(s) ☐ Bone ☐ Lung ☐ Liver ☐ Brain ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 215a, otherwise, skip to Question 216.***
215a	Other metastatic/ recurrent site	_____	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
216	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
217	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
218	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
219	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
220	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
221	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.



Enrollment: Prostate

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
222	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
223	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
Additional Metastatic/Recurrent Tumor Prognostic/Predictive/Lifestyle Features for Additional Metastatic/Recurrent Tumor Prognosis or Responsiveness to Treatment ***(Note: Questions 165-200 may be repeated to capture clinical molecular characterization information for additional metastatic/recurrent biospecimens.)***				
Metastatic/Recurrent Tumor Model Information				
224	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
225	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
226	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
227	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
228	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Additional Metastatic/Recurrent Biospecimen Tumor Model Information (if applicable)				
229	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
230	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
231	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
232	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
233	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Other Biospecimen Information				
234	Are you submitting an OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an OTHER tissue sample (e.g. pre-malignant, non-malignant, or dysplastic tissue, etc.) was collected for HCMI for this case. ***Note: If yes, proceed to Question 235.***



Enrollment: Prostate

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
235	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
236	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
237	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
238	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
239	Other method of cancer sample procurement	☐ Core needle biopsy ☐ Fine needle aspirate ☐ TURP including all forms of enucleation ☐ Salvaged radical prostatectomy ☐ Other Method (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 239a, otherwise, skip to Question 240. If TURP was performed, proceed to Question 240, otherwise, skip to Question 246.***
239a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
240	For TURP specimens, number of positive chips	_____	2431688	Provide the number of chips involved by invasive prostate carcinoma, in a transurethral resection specimen.
241	For TURP specimens, number of total chips	_____	2431624	Provide the total number of chips in a specimen of prostate removed by transurethral resection.
242	For TURP specimens, estimated percentage of prostatic tissue involved by tumor	_____%	2431904	Provide the percentage of prostatic tissue which is involved by invasive prostate carcinoma, in a transurethral resection specimen.
243	For enucleation specimens, estimated percentage of prostatic tissue involved by tumor	_____%	6831339	Provide the percentage of prostatic tissue which is involved by tumor.
244	For enucleation specimens, tumor size (dominant nodule, if present)	_____mm	6831608	Provide the numeric value in mm for the size of the dominant (if present) tumor nodule.
245	For enucleation specimens, additional dimensions (millimeters)	_____mm	6831609	Provide the numeric value in mm for an additional dimension of the tumor.
246	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
247	Tissue type	☐ Pre-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 247a, otherwise, skip to Question 248.***
247a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.



Enrollment: Prostate

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
248	Anatomic site of OTHER tissue	☐ Prostate ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 248a, otherwise, skip to Question 249.***
248a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.
249	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
250	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Additional OTHER biospecimen Information (if applicable)				
251	Are you submitting an additional OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an additional OTHER tissue sample (pre-malignant, non-malignant, or dysplastic tissue, etc.) is being submitted for HCMI for this case. ***Note: If yes, proceed to Question 252, otherwise, skip to Question 268.***
252	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
253	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
254	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
255	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
256	Other method of cancer sample procurement	☐ Core needle biopsy ☐ Fine needle aspirate ☐ TURP including all forms of enucleation ☐ Salvaged radical prostatectomy ☐ Other Method (specify, CDE ID: 6587399)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 256a, otherwise, skip to Question 263. If TURP was performed, proceed to Question 257, otherwise, skip to Question 263.***
256a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
257	For TURP specimens, number of positive chips	_____	2431688	Provide the number of chips involved by invasive prostate carcinoma, in a transurethral resection specimen.
258	For TURP specimens, number of total chips	_____	2431624	Provide the total number of chips in a specimen of prostate removed by transurethral resection.



Enrollment: Prostate

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
259	For TURP specimens, estimated percentage of prostatic tissue involved by tumor	_____%	2431904	Provide the percentage of prostatic tissue which is involved by invasive prostate carcinoma, in a transurethral resection specimen.
260	For enucleation specimens, estimated percentage of prostatic tissue involved by tumor	_____%	6831339	Provide the percentage of prostatic tissue which is involved by tumor.
261	For enucleation specimens, tumor size (dominant nodule, if present)	_____mm	6831608	Provide the numeric value in mm for the size of the dominant (if present) tumor nodule.
262	For enucleation specimens, additional dimensions (millimeters)	_____mm	6831609	Provide the numeric value in mm for an additional dimension of the tumor.
263	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
264	Tissue type	☐ Pre-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 264a, otherwise, skip to Question 265.***
264a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
265	Anatomic site of OTHER tissue	☐ Prostate ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 265a, otherwise, skip to Question 266.***
265a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.
266	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
267	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Other Tissue Model Information				
268	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
269	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
270	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
271	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.



Enrollment: Prostate

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
272	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.
Additional Other Tissue Model Information (if applicable)				
273	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
274	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
275	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
276	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
277	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.



Enrollment: Rare

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Form Notes: An Enrollment Form should be completed for each HCMI case upon qualification notice from Leidos. All information provided on this form should include activity from the Date of Initial Pathologic Diagnosis to the most recent Date of Last Contact with the patient. The Rare Cancer Enrollment Form should be used for the following cancer types: Bladder Cancer, Chordoma, Duodenal Gastrinoma, Epithelioid Sarcoma, Extrahepatic Cholangiocarcinoma, Gallbladder Cancer, Malignant Spindle Cell Neoplasm, Mullerian Carcinoma, Small Intestine Cancer, and Thyroid Cancer.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	☐ Initial pathologic diagnosis ☐ Sample procurement ☐ First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.
Patient Information				
4	Gender	☐ Male ☐ Female ☐ Unspecified	2200604	Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
5	Height	_____	649	Provide the patient's height, in centimeters.
6	Weight	_____	651	Provide the patient's weight, in kilograms.
7	Body mass index (BMI)	_____	2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
8	Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown ☐ Not reported	2192199	Provide the patient's race using the defined categories. **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 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. **Black or African American:** A person having origins in any of the black racial groups of Africa. **Native Hawaiian or other Pacific Islander:** A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island. **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
9	Ethnicity	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Not reported	2192217	Provide the patient's ethnicity using the defined categories. **Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. **Not Hispanic or Latino:** A person not meeting the definition of Hispanic or Latino.
10	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.



Enrollment: Rare

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
11	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. ***Note: If the patient's age is greater than 32,872 days (90 years), please enter 32,872.***
12	Year of birth	_____	2896954	Provide the year of the patient's birth. If the patient was born prior to 1928, insert the date 1928.
13	Family history of cancer	☐ Same ☐ Different ☐ None ☐ Unknown	5832923	Has a first-degree relative of the patient been diagnosed with a cancer of the same or a different type?
14	Smoking history	☐ Lifelong non-smoker (<100 cigarettes smoked in a lifetime) ☐ Current smoker (includes daily and non-daily smokers) ☐ Current reformed smoker (duration not specified) ☐ Current reformed smoker for >15 years ☐ Current reformed smoker for ≤15 years	2181650	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories.
15	Daily alcohol consumption (drinks per day)	_____	3124961	Indicate the patient's daily alcohol consumption as self-reported by the patient.
15a	Frequency of alcohol consumption days per week	_____	3114013	Provide the average number of days each week that the patient consumes an alcoholic beverage.
16	Infection history?	☐ Yes ☐ No ☐ Unknown	2816879	Indicate whether the patient has a history of relevant infectious disease.
16a	Specify relevant infectious disease	_____	3233643	Specify the name of the relevant infectious disease.
17	Asbestos exposure?	☐ Yes ☐ No ☐ Unknown	1253	Indicate whether the patient has been exposed to asbestos.
18	Metastasis at diagnosis assessment status	☐ Metastatic ☐ Non-metastatic (confirmed) ☐ Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor. ***Note: If metastatic at diagnosis, proceed to Question 18a, otherwise, skip to Question 19.***
18a	Metastatic site(s) at diagnosis	☐ Ascites ☐ Lung ☐ Bone ☐ Lymph node(s) ☐ Brain ☐ Skin ☐ Kidney ☐ Spinal cord ☐ Liver ☐ Other (specify)	3029815	Indicate the site(s) of metastasis at the time of diagnosis of the primary tumor. ***Note: If the anatomic site of tumor tissue is not listed, proceed to Question 18a, otherwise, skip to Question 19.***
18b	Specify metastatic site(s)	_____	3128033	If the site of metastasis is not included on the provided list, specify the site of metastasis.
Biospecimen Information				
19	Tissue sample type(s) collected for HCMI for this case	☐ Normal tissue ☐ Primary tumor ☐ Metastatic ☐ Recurrent ☐ Other tissue	2006911	Please select all the tissue sample types submitted for HCMI with this case.
20	Number of NORMAL tissue biospecimens collected for HCMI for this case	_____	6584256	Please provide the number of normal tissue specimens obtained for HCMI for this case. ***Note: This number is expected to be "1".***



Enrollment: Rare

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
21	Number of PRIMARY cancer tissue biospecimens collected for HCMI model development for this case	_____	6584257	Please provide the number of primary tumor specimens obtained for HCMI for this case. ***Note: A single primary tumor biospecimen obtained that is portioned for both sequencing and model generation counts as 1 single primary tumor specimen. This number is expected to be "1".***
22	Number of METASTATIC/ RECURRENT cancer tissue biospecimens collected for HCMI model development for this case	_____	6584258	Please provide the number of metastatic and/or recurrent cancer biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
23	Number of OTHER tissue biospecimens collected for HCMI model development for this case	_____	6584259	Please provide the number of pre-malignant, non-malignant, or dysplastic tissue biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
24	Total number of tissue biospecimens collected for HCMI for this case	_____	6584271	Please provide the total number of tissue biospecimens collected for HCMI for this case. ***Note: This number should be the sum of the normal, primary tumor, metastatic/recurrent tumor, and other biospecimen counts above.***
Normal Control Information				
25	Normal tissue biospecimen ordinal	_____	6584264	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
26	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
27	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.



Enrollment: Rare

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
28	Type of normal control	☐ Whole blood ☐ Buccal cells ☐ Buffy coat ☐ Lymphocytes ☐ Extracted DNA from blood ☐ Extracted DNA from saliva ☐ Extracted DNA from buccal cells ☐ Extracted DNA from normal tissue (specify site) ☐ FFPE non-neoplastic tissue (specify site) ☐ Non-neoplastic tissue (specify site) ☐ Adjacent (specify site) ☐ Normal tissue from other anatomic site (specify site)	3081936	Indicate the type of normal control submitted for this case. ***Note: If normal tissue was not submitted, select 'Not applicable'. If non-neoplastic tissue, adjacent tissue, or normal tissue from another anatomic site was submitted as the normal control, proceed to Question 28a, otherwise, skip to Question 29.***
28a	Other anatomic site of normal tissue	_____	3288189	If non-neoplastic tissue, adjacent tissue, or normal tissue from another anatomic site was submitted as the normal control, provide the anatomic site of the normal tissue.
29	Distance from tumor to normal control tissue (if not blood)	☐ Adjacent (< or = 2cm) ☐ Distal (>2cm) ☐ Unknown ☐ Not applicable	3088708	Indicate the distance from the site of normal tumor collection to the primary tumor. ***Note: If normal tissue was not submitted, select 'Not applicable'.***
30	Normal tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Fresh ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the normal tissue sample collected for molecular characterization.
Primary Tumor Biospecimen Information				
31	ICD-10 code for model tumor	☐ C17.0 ☐ C17.1 ☐ C17.2 ☐ C17.3 ☐ C17.8 ☐ C17.9 ☐ C23 ☐ C24.0 ☐ C24.8 ☐ C24.9 ☐ C41.0 ☐ C41.2 ☐ C41.4 ☐ C49 ☐ C49.1 ☐ C49.2 ☐ C49.8 ☐ C49.9 ☐ C56.1 ☐ C56.2 ☐ C56.9 ☐ C67.0 ☐ C67.1 ☐ C67.2 ☐ C67.3 ☐ C67.4 ☐ C67.5 ☐ C67.6 ☐ C67.7 ☐ C67.8 ☐ C67.9 ☐ C73 ☐ C77.0 ☐ C77.1 ☐ C77.2 ☐ C77.3 ☐ C77.4 ☐ C77.5 ☐ C77.8 ☐ C77.9 ☐ C78.2 ☐ C78.4 ☐ C78.7 ☐ C78.8 ☐ C79.0 ☐ C79.1 ☐ C79.2 ☐ C79.3 ☐ C79.4 ☐ C79.6 ☐ C79.8 ☐ Other (specify)	3226287	Provide the ICD-10 code for the primary tumor as used to generate the ID3 for this subject. ***Note: If the ICD-10 code of the primary tumor is not listed, proceed to Question 31a, otherwise, skip to Question 32.***
31a	Other ICD-10 code	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.



Enrollment: Rare

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
32	Tumor Morphology	☐ 8013/3 ☐ 8020/3 ☐ 8031/3 ☐ 8032/3 ☐ 8041/3 ☐ 8051/3 ☐ 8070/3 ☐ 8074/3 ☐ 8083/2 ☐ 8120/3 ☐ 8131/3 ☐ 8140/3 ☐ 8144/3 ☐ 8153/3 ☐ 8240/3 ☐ 8243/3 ☐ 8244/3 ☐ 8246/3 ☐ 8249/3 ☐ 8310/3 ☐ 8330/3 ☐ 8430/3 ☐ 8345/3 ☐ 8346/3 ☐ 8480/3 ☐ 8490/3 ☐ 8510/3 ☐ 8560/3 ☐ 8588/3 ☐ 8589/3 ☐ 8801/3 ☐ 8804/3 ☐ 8950/3 ☐ 9370/3 ☐ 9371/3 ☐ 9372/3 ☐ Other (specify)	3226275	Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor. ***Note: If the ICD-O-3 histology code of the primary tumor is not listed, proceed to Question 32a, otherwise, skip to Question 33.***
32a	Specify other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.
33	Tissue or organ of origin	☐ Bladder ☐ Bone ☐ Connective tissue ☐ Extrahepatic bile duct ☐ Gallbladder ☐ Ovary ☐ Small intestine ☐ Skin ☐ Thyroid gland ☐ Uterus ☐ Other site (specify)	3427536	Using the patient's pathology/laboratory report, select the primary site of the disease. ***Note: If the primary site of the disease is not listed, proceed to Question 33a, otherwise skip to Question 34.***
33a	Other tissue or organ of origin	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gum ☐ Head, face or neck ☐ Heart Other ill-defined sites ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Vagina ☐ Vulva	3427536	If the primary site of the disease is not included on the previous list, provide the primary site of the disease.



Enrollment: Rare

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
34	Histological Type	☐ Bladder cancer ☐ Bone Cancer ☐ Chordoma ☐ Duodenal gastrinoma ☐ Epithelioid sarcoma ☐ Extrahepatic cholangiocarcinoma ☐ Gallbladder cancer ☐ Malignant spindle cell neoplasm ☐ Mullerian carcinoma ☐ Small intestine cancer ☐ Thyroid cancer ☐ Other (specify)	3081932	Select the surgical pathology text description of the histological tumor type. ***Note: If the histological tumor type is not listed, proceed to Question 34a, otherwise, skip to Question 35.***
34a	Other histological type	_____	3294805	If the traditional surgical pathology text description of the histological tumor type is not included on the previous list, please specify the histological type.
35	Prior malignancy (of the same cancer type)	☐ Yes ☐ No ☐ Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
36	Prior malignancy (other cancer type)	☐ Yes ☐ No ☐ Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.
37	AJCC cancer staging edition	☐ 1st ☐ 2nd ☐ 3rd ☐ 4th ☐ 5th ☐ 6th ☐ 7th ☐ 8th	2722309	Select the AJCC staging handbook edition used to stage the patient's primary tumor.
38	AJCC clinical stage group	☐ Stage 0 ☐ Stage 0a ☐ Stage 0is ☐ Stage I ☐ Stage IA ☐ Stage IA1 ☐ Stage IA2 ☐ Stage IA3 ☐ Stage IB ☐ Stage IB1 ☐ Stage IB2 ☐ Stage II ☐ Stage IIA ☐ Stage IIB ☐ Stage IIC ☐ Stage III ☐ Stage IIIA ☐ Stage IIIB ☐ Stage IIIC ☐ Stage IV ☐ Stage IVA ☐ Stage IVB ☐ Stage IVC ☐ Stage IS ☐ Stage Tis ☐ Stage X ☐ Not applicable	3440332	Using the patient's pathology/laboratory report, select the clinical stage group of the primary tumor as defined by the American Joint Committee on Cancer (AJCC), if applicable.
39	AJCC pathologic spread: Primary tumor (pT)	☐ T0 ☐ T1 ☐ T1a ☐ T1a1 ☐ T1a2 ☐ T1b ☐ T1b1 ☐ T1b2 ☐ T1c ☐ T1mi ☐ T2 ☐ T2a ☐ T2a1 ☐ T2a2 ☐ T2b ☐ T2c ☐ T2d ☐ T3 ☐ T3a ☐ T3b ☐ T3c ☐ T3d ☐ T4 ☐ T4a ☐ T4b ☐ T4c ☐ T4d ☐ T4e ☐ T5 ☐ Tis ☐ Tis (AIS) ☐ Tis (DCIS) ☐ Tis (LCIS) ☐ Tis (Paget's) ☐ Tis (SCIS) ☐ TX ☐ Not applicable	3045435	Using the patient's pathology/laboratory report, select the code for the pathologic T (primary tumor) as defined by the American Joint Committee on Cancer (AJCC).



Enrollment: Rare

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
40	AJCC pathologic spread: Lymph nodes (pN)	☐ N0 ☐ N0 (i+) ☐ N0 (i-) ☐ N0 (mol+) ☐ N0 (mol-) ☐ N1 ☐ N1a ☐ N1b ☐ N1bI ☐ N1bII ☐ N1bIII ☐ N1bIV ☐ N1c ☐ N1mi ☐ N2 ☐ N2a ☐ N2b ☐ N2c ☐ N3 ☐ N3a ☐ N3b ☐ N3c ☐ N4 ☐ NX ☐ Not applicable	3203106	Using the patient's pathology/laboratory report, select the code for the pathologic N (nodal) as defined by the American Joint Committee on Cancer (AJCC).
41	AJCC pathologic spread: Distant metastases (pM)	☐ M0 ☐ M1 ☐ M1a ☐ M1b ☐ M1c ☐ M2 ☐ MX ☐ Not applicable	3045439	Using the patient's pathology/laboratory report, select the code for the pathologic M (metastasis) as defined by the American Joint Committee on Cancer (AJCC).
42	AJCC tumor stage (pathological)	☐ 0 ☐ 0a ☐ 0is ☐ I ☐ IA ☐ IA1 ☐ IA2 ☐ IB ☐ IB1 ☐ IB2 ☐ IC ☐ II ☐ IIA ☐ IIA1 ☐ IIA2 ☐ IIB ☐ IIC ☐ III ☐ IIIA ☐ IIIB ☐ IIIC ☐ IV ☐ IVA ☐ IVB ☐ IVC ☐ Tis ☐ X ☐ Not applicable	3065862	Using the patient's pathology/laboratory report, in conjunction with the patient's medical record, select the stage as defined by the American Joint Committee on Cancer (AJCC).
43	Tumor grade	☐ G1-Well differentiated ☐ G2-Moderately differentiated ☐ G3-Poorly differentiated ☐ G4-Undifferentiated ☐ GB-Borderline histologic grade ☐ GX-Unknown ☐ Not applicable	2785839	Using the patient's pathology/laboratory report, select the grade of the primary tumor, if applicable.
44	Lymphatic invasion present?	☐ Yes ☐ No ☐ Unknown	64171	Indicate if malignant cells are present in small or thin-walled vessels, suggesting lymphatic involvement.
45	Is necrosis present?	☐ Yes ☐ No ☐ Unknown	64740	Indicate whether there is evidence of localized death of living cells within the tumor.
46	Venous invasion present?	☐ Yes ☐ No ☐ Unknown	64358	Indicate whether venous invasion was present in the tumor specimen.
47	Number of positive lymph nodes	_____	89	Provide the number of lymph nodes with disease involvement.
48	Number of lymph nodes tested	_____	3	Provide the total number of lymph nodes tested for the presence of cancer cells.



Enrollment: Rare

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Primary Tumor Sample Information				
49	Are you submitting a primary tumor tissue sample for this case?	☐ Yes ☐ No		***Note: If yes, proceed to question 50.***
50	Primary tumor biospecimen ordinal	_____	6584265	Please provide a number to identify which biospecimen this is in the sequence.
51	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
52	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
53	Sample represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this primary tumor specimen represent the PRIMARY DIAGNOSIS for this Case ID3?
54	Specify the ICD-10 code	_____	3226287	Provide the ICD-10 code for the primary tumor used to generate the model submitted to HCMI.
55	Tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Fresh ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the tumor tissue sample collected for molecular characterization.
56	ICD-O-3 topography code for anatomic site from which the tumor was obtained	_____	6154743	Provide ICD-O-3 topography code corresponding to the anatomic site of the tumor tissue sample used to generate the model for HCMI. (http://codes.iarc.fr/topography)
57	Method of cancer sample procurement	☐ Tumor resection ☐ Biopsy ☐ Core needle biopsy ☐ Incisional biopsy ☐ Fine needle aspiration ☐ Punch biopsy ☐ Other (specify)	3103514	Provide the procedure performed to obtain the primary tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 57a, otherwise, skip to Question 58.***
57a	Specify the other method of tumor sample procurement	_____	2006730	Specify the procedure performed to obtain the primary tumor tissue, if not included in the previous list.
58	Number of days from index date to date of tumor sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the tumor tissue submitted for HCMI.
59	Tumor tissue type	☐ Primary ☐ Additional Primary ☐ NOS	3288124	Provide the primary tumor tissue type for this sample.



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Primary Tumor Clinical Molecular Analysis Information				
Question	**Question Text**	**Data Entry Options**	**CDE ID**	**Instruction Text**
60	MMR status	☐ Evidence of MMR mutation by sequencing ☐ Evidence of MMR protein loss by IHC ☐ MMR loss evidence hypermutation phenotype (>10mutations/Mb) ☐ No evidence of MMR alteration	6002208	Indicate the patient's Mismatch Repair (MMR) gene mutation status.
61	MYCN gene amplification status	☐ Amplified ☐ Not amplified ☐ Not done ☐ Unknown	4616052	Indicate the amplification status of the MYCN gene.
62	MLH1 promoter methylation status	☐ MLH1 promoter hypermethylation present ☐ MLH1 promoter hypermethylation absent ☐ MLH1 promoter hypermethylation not assessed ☐ Indeterminate	6033150	Indicate the methylation status of the MLH1 promoter.
63	Was HER2 FISH/CISH performed?	☐ Yes ☐ No ☐ Unknown	6063447	Indicate whether HER2 was assessed by fluorescence in situ hybridization (FISH) or chromogenic in situ hybridization (CISH). ***Note: If yes, proceed to Questions 63a-e.***
63a	HER2 status by FISH/CISH	☐ Amplified ☐ Not amplified ☐ Equivocal	2854089	Select the HER2 status as assessed by FISH/CISH.
63b	HER2 copy number	_____	3133738	If HER2 copy number testing was performed, provide the average number of HER2 fluorescence in situ hybridization (FISH) signals for the patient's primary tumor.
63c	Centromere 17 copy number	_____	3104295	If Centromere 17 copy number testing was performed, provide the average number of Centromere 17 fluorescence in situ hybridization (FISH) signals for the patient's primary tumor.
63d	Number of cells counted for HER2 and Centromere 17 copy numbers	_____	3087902	Provide the total number of cells counted to assess HER2 and Centromere 17 copy numbers.
63e	HER2/Centromere 17 signal ratio	_____	2497552	If HER2 and Centromere 17 copy number analyses were performed by FISH, provide the ratio of the outcomes of these tests.
Primary Tumor Mutational Analyses				
64	Was mutation analysis performed for any of the following genes?	☐ ALK ☐ BRAF ☐ CDKN2A ☐ EGFR ☐ GNAS ☐ H3 K27 ☐ IDH1/2 ☐ KRAS ☐ PIK3CA ☐ PTEN ☐ TP53		Select the gene(s) for which mutation analysis was performed. ***Note: If ALK is selected, proceed to Question 65; if BRAF is selected, proceed to Question 66; If CDKN2A is selected, proceed to Question 67; If EGFR is selected, proceed to Question 68; If GNAS is selected, proceed to Question 69; If H3 K27 is selected, proceed to Question 70; If IDH1/2 is selected, proceed to Question 71; If KRAS is selected, proceed to Question 72; If PIK3CA is selected, proceed to Question 73; If PTEN is selected, proceed to Question 74; If TP53 is selected, proceed to Question 75.***
65	Was a mutation in ALK identified?	☐ Yes ☐ No	3774202	Indicate whether a mutation in ALK was identified. ***Note: If yes, proceed to Question 65a.***
65a	If ALK mutation identified, which one?	☐ F1174L ☐ K1062M ☐ R1275Q ☐ T1087I ☐ F1174C ☐ F1174V ☐ F1245L ☐ Other (specify)	6060279	Select the ALK mutation identified. ***Note: If the ALK mutation is not listed, proceed to Question 65b.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
65b	Other ALK mutation	_____	6101680	If the ALK mutation identified is not included in the provided list, specify the ALK mutation identified.
66	Was a mutation in BRAF identified?	☐ Yes ☐ No	6061809	Indicate whether a mutation in BRAF was identified through mutation analysis. ***Note: If yes, proceed to Question 66a.***
66a	If BRAF mutation identified, which one?	☐ V600E ☐ V600D ☐ V600K ☐ V600R ☐ K601E ☐ Other (specify)	6061810	Indicate the specific BRAF mutation identified. ***Note: If the BRAF mutation is not listed, proceed to Question 66b.***
66b	Other BRAF mutation	_____	6101687	If the BRAF mutation is not included in the list provided, specify the BRAF mutation identified.
66c	What sequencing assay was used to identify the BRAF mutation?	☐ Next generation targeted sequencing ☐ Whole exome sequencing ☐ Other (specify)	6003729	Select the sequencing assay used to identify the somatic mutation. ***Note: If the sequencing assay is not listed, proceed to Questions 66d.***
66d	Other sequencing assay	_____	6002204	If the sequencing assay is not included in the provided list, specify the other sequencing assay.
67	Was a mutation in CDKN2A identified?	☐ Yes ☐ No	6063534	Indicate whether a mutation in CDKN2A was identified through mutation analysis. ***Note: If yes, proceed to question 67a.***
67a	If CDKN2A mutation identified, which one?	☐ A30V ☐ V51D ☐ V51I ☐ H83P ☐ H83Y ☐ D108H ☐ D108Y ☐ L130Q ☐ A147T ☐ A148T ☐ Other (specify	6063732	Indicate the specific CDKN2A mutation identified. ***Note: If the CDKN2A mutation is not listed, proceed to Question 67b.***
67b	Other CDKN2A mutation(s)	_____	6101684	If the CDKN2A mutation identified is not provided in the previous list, specify the CDKN2A mutation.
68	Was a mutation in EGFR identified?	☐ Yes ☐ No	6063530	Indicate whether a mutation in EGFR was identified through mutation analysis. ***Note: If yes, proceed to Question 68a.***
68a	If EGFR mutation identified, which one?	☐ G719X ☐ T790M ☐ C797S ☐ L858R ☐ L861Q ☐ Exon 19 deletion ☐ Exon 20 insertion ☐ Other (specify	3147627	Indicate the specific EGFR mutation identified. ***Note: If the EGFR mutation is not listed, proceed to Question 68b.***
68b	Other EGFR mutation(s)	_____	4173882	If the EGFR mutation identified is not provided in the previous list, specify the EGFR mutation.
69	Was a mutation in GNAS identified?	☐ Yes ☐ No	5983161	Indicate whether a mutation in GNAS was identified through mutation analysis. ***Note: If yes, proceed to Question 69a.***
69a	If GNAS mutation identified, which one?	☐ Q125R ☐ R160C ☐ R201C ☐ R201H ☐ R201S ☐ Q227E ☐ Q227L ☐ Q227P ☐ Q227R ☐ Other (specify	6063733	Indicate the specific GNAS mutation identified. ***Note: If the GNAS mutation is not listed, proceed to Question 69b.***
69b	Other GNAS mutation(s)	_____	6101685	If the GNAS mutation identified is not provided in the previous list, specify the GNAS mutation.
70	Was a mutation in H3 K27 identified?	☐ Yes ☐ No	6002202	Indicate whether H3 K27 mutation was identified. ***Note: If yes, proceed to Question 70a.***
70a	If H3 K27 mutation identified, in which variant was it found?	☐ H3.1 ☐ H3.3 ☐ Other	6002205	Select the H3 K27 mutation identified.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
71	Was a mutation in IDH1/2 identified?	☐ Yes ☐ No	6002200	Indicate whether an IDH1 or IDH2 mutation was identified at testing. ***Note: If yes, proceed to Question 71a.***
71a	If IDH1/2 mutation identified, which one?	☐ IDH1 R132H ☐ IDH1 R132C ☐ IDH1 R132S ☐ IDH1 R132G ☐ IDH1 R132L ☐ IDH2 R172W ☐ IDH2 R172K ☐ IDH2 R172M ☐ Other (specify)	6002206	Select the mutation identified in IDH1/2. ***Note: If the IDH1/2 mutation is not listed, proceed to Question 71b.***
71b	Other IDH1/2 mutation	_____	6002207	If the mutation in IDH1/2 is not included in the provided list, specify the mutation in IDH1/2.
71c	What sequencing assay was used to identify the IDH1/2 mutation?	☐ Next generation targeted sequencing ☐ Whole exome sequencing ☐ Not performed ☐ Other (specify)	6003729	Select the sequencing assay used to identify the somatic mutation. ***Note: If the sequencing assay is not listed, proceed to Question 71d.***
71d	Other sequencing assay	_____	6002204	If the sequencing assay is not included in the provided list, specify the other sequencing assay.
72	Was a mutation in KRAS identified?	☐ Yes ☐ No	6060081	Indicate whether a mutation in KRAS was identified through mutation analysis. ***Note: If yes, proceed to Question 72a.***
72a	If KRAS mutation identified, which one?	☐ G12A ☐ G12C ☐ G12D ☐ G12R ☐ G12S ☐ G12V ☐ G13A ☐ G13C ☐ G13D ☐ G13R ☐ G13V ☐ Q61H ☐ Q61L ☐ A146T ☐ Other (specify)	6060083	Indicate the specific KRAS mutation identified. ***Note: If the KRAS mutation is not listed, proceed to Question 72b.***
72b	Other KRAS mutation	_____	6101691	If the KRAS mutation identified is not provided in the previous list, specify the KRAS mutation.
73	Was a mutation in PIK3CA identified?	☐ Yes ☐ No	6063524	Indicate whether a mutation in PIK3CA was identified through mutation analysis. ***Note: If yes, proceed to Question 73a.***
73a	If PIK3CA mutation identified, in what exon?	☐ 9 ☐ 20 ☐ Other (specify)	6063735	Indicate the specific exon of the PIK3CA gene in which the mutation was identified. ***Note: If the PIK3CA mutation is not listed, proceed to Question 73b.***
73b	Other PIK3CA mutation	_____	6101688	If the specific exon of the PIK3CA gene mutation abnormality identified was not included in the previous list, please specify the exon.
74	Was a mutation in PTEN identified?	☐ Yes ☐ No	6063529	Indicate whether a mutation in PTEN was identified through mutation analysis. ***Note: If yes, proceed to Question 74a.***
74a	If PTEN mutation identified, which one?	☐ Exon 1-9 mutation present ☐ Cannot be determined ☐ Other (specify	6063736	Indicate whether a mutation in exon 1-9 of PTEN was identified. ***Note: If the PIK3CA mutation is not listed, proceed to Question 74b.***
74b	Other PTEN mutation	_____	6101689	If the PTEN gene mutation identified is not in exons 1-9, please specify the exon.
75	Was a mutation in TP53 identified?	☐ Yes ☐ No	6063523	Indicate whether a mutation in TP53 was identified through mutation analysis. ***Note: If yes, proceed to Question 75a.***
75a	If TP53 mutation identified, which one?	☐ R175H ☐ R213L ☐ Y220C ☐ C238Y ☐ G245D ☐ G245S ☐ R248Q ☐ R248W ☐ G266E ☐ G266V ☐ V272M ☐ R273C ☐ R273H ☐ R273L ☐ R282G ☐ R282W ☐ Other (specify	6063731	Indicate the specific TP53 mutation identified. ***Note: If the TP53 mutation is not listed, proceed to Question 75b.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
75b	Other TP53 mutation(s)	_____	6101683	If the TP53 mutation identified is not provided in the previous list, specify the TP53 mutation.
75c	What sequencing assay was used to identify the TP53 mutation?	☐ Next generation targeted sequencing ☐ Whole exome sequencing ☐ Not performed ☐ Other (specify)	6003729	Select the sequencing assay used to identify the somatic mutation. ***Note: If the sequencing assay is not listed, proceed to Question 75d.***
75d	Other sequencing assay	_____	6002204	If the sequencing assay is not included in the provided list, specify the other sequencing assay.
Primary Tumor Protein Expression Information				
76	Was IHC performed in any of the following proteins?	☐ BRAF V600E ☐ ER ☐ H3 K27M ☐ HER2 ☐ IDH1 R132H ☐ MLH1 ☐ MSH2 ☐ MSH6 ☐ PMS2 ☐ PD-L1 ☐ PR ☐ PTEN ☐ SMAD4		Select the protein(s) for which IHC was performed. ***Note: If BRAF V600E is selected, proceed to Question 77; If ER is selected, proceed to Question 78. If H3 K27M is selected, proceed to Question 79; If HER2 is selected, proceed to Question 80; If IDH1 R132H is selected, proceed to Question 81; If MLH1 is selected, proceed to Question 82; If MSH2 is selected, proceed to Question 83; If MSH6 is selected, proceed to Question 84; If PMS2 is selected, proceed to Question 85; If PD-L1 is selected, proceed to Question 86; If PR is selected, proceed to Question 87; If PTEN is selected, proceed to Question 88; if SMAD4 is selected, proceed to Question 89.***
77	BRAF V600E expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6428124	Indicate the expression of BRAF V600E by immunohistochemistry (IHC).
78	Estrogen Receptor (ER) Allred score	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7	2419219	Indicate the numeric Allred score (cell staining percentage plus intensity) for estrogen receptor.
79	H3 K27M expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6002203	Indicate the expression of H3 K27M by immunohistochemistry (IHC).
80	HER2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	2957563	Indicate the expression of HER2 as assessed by immunohistochemistry (IHC).
81	IDH1 R132H expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063674	Indicate the expression of IDH1 R132H as assessed by immunohistochemistry (IHC).
82	MLH1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063668	Indicate the status of MLH1 protein expression as determined by immunohistochemistry (IHC).
83	MSH2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063669	Indicate the status of MSH2 protein expression as determined by immunohistochemistry (IHC).
84	MSH6 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063671	Indicate the status of MSH6 protein expression as determined by immunohistochemistry (IHC).
85	PMS2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063670	Indicate the status of PMS2 protein expression as determined by immunohistochemistry (IHC).
86	PD-L1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	4798631	Indicate the status of PD-L1 protein expression as determined by immunohistochemistry (IHC).
87	Progesterone receptor (PR) expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063673	Indicate the expression of progesterone receptor as assessed by immunohistochemistry (IHC).



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
88	PTEN expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063672	Indicate the status of PTEN protein expression as determined by immunohistochemistry (IHC).
89	SMAD4 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063676	Indicate the status of SMAD4 protein expression as determined by immunohistochemistry (IHC).
Primary Tumor Model Information				
90	Primary model biospecimen ordinal	_____	6594596	Please provide a number to identify which biospecimen this is in the sequence. ***This number is expected to be "1".***
91	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
92	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
93	Model represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this MODEL represent the PRIMARY DIAGNOSIS for this Case ID3?
94	Model's primary tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the PRIMARY TUMOR TISSUE from which this model is derived.
95	Model's primary tumor biospecimen ordinal	_____	6584265	Enter the biospecimen ordinal of the PRIMARY TUMOR TISSUE from which this model is derived.
Treatment Information				
96	History of neoadjuvant treatment	☐ No ☐ Yes; radiation prior to resection ☐ Yes; pharmaceutical treatment prior to resection ☐ Yes; both radiation and pharmaceutical treatment prior to resection ☐ Unknown	3382737	Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment. ***Note: Radiation therapy is addressed in Questions 106-107. Pharmaceutical therapy is addressed in Questions 97-105.***
97	Neoadjuvant chemotherapy type	☐ Cytotoxic chemotherapy ☐ Hormonal ☐ Immunotherapy (cellular and immune checkpoint) ☐ Targeted therapy (small molecule inhibitors and targeted antibodies) ☐ Not applicable	5832928	Select all neoadjuvant chemotherapy types that were administered to the patient. ***Note: Cytotoxic chemotherapy is addressed in Questions 98-99. Hormonal therapy is addressed in Questions 100-101. Immunotherapy is addressed in Questions 102-103. Targeted therapy is addressed in Questions 104-105.***
98	Neoadjuvant chemotherapeutic regimen	☐ 5-fluorouracil ☐ Albumin-bound paclitaxel ☐ Capecitabine ☐ Carboplatin ☐ Cisplatin ☐ Cyclophos-phamide ☐ Docetaxel ☐ Epirubicin ☐ Eribulin ☐ Gemcitabine ☐ Ixabepilone ☐ Lapatinib ☐ Liposomal Doxorubicin ☐ Methotrexate ☐ Mitoxantrone ☐ Neratinib ☐ Paclitaxel ☐ T-DM1 ☐ Trastuzumab ☐ Vinorelbine ☐ Other (specify) ☐ Chemotherapy not given	2853313	Select all chemotherapeutics used for neoadjuvant therapy. ***Note: If neoadjuvant chemotherapy was not given, skip to Question 100. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 98a, otherwise, skip to Question 99.***



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
98a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapies administered.
99	Days to neoadjuvant chemotherapy treatment from index date	_____	5102411	Provide the number of days from index date to the date of treatment with neoadjuvant chemotherapy.
100	Specify hormone therapy	_____	2405358	Provide the name of the hormone therapy administered to the patient.
101	Days to hormone therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with hormone therapy.
102	Specify immunotherapy	_____	2953828	Provide the name of the immunotherapy administered to the patient.
103	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
104	Specify targeted therapy	_____	4308476	Provide the name of the targeted therapy administered to the patient.
105	Days to targeted therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with targeted therapy.
106	Radiation therapy administered type	☐ 2D conventional ☐ 3D conformal ☐ Brachytherapy HDR ☐ Brachytherapy LDR ☐ IMRT ☐ Proton Beam ☐ Stereotactic Body RT ☐ Stereotactic Radiosurgery ☐ WBRT ☐ Other (specify) ☐ Unspecified ☐ Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. ***Note: If radiation therapy was not administered, skip the remaining questions. If the radiation therapy is not listed, proceed to Question 106a, otherwise, skip to Question 107.***
106a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
107	Days to radiation treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with radiation therapy.
Metastatic/Recurrent Tumor Biospecimen Information				
108	Are you submitting a metastatic/ recurrent tumor tissue sample?	☐ Yes ☐ No		Indicate whether a metastatic/recurrent tumor biospecimen was collected for this ID3 case. ***Note: If yes, proceed to Question 109. If submitting an OTHER tissue sample, proceed to Question 152.***
109	Metastatic tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1", the second should be number "2", etc.***
110	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
111	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
112	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Fresh ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
113	Number of days from index date to date of diagnosis of metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic/recurrent disease.
114	Method of metastatic/ recurrent cancer sample procurement	☐ Tumor resection ☐ Biopsy ☐ Core needle biopsy ☐ Incisional biopsy ☐ Fine needle aspiration ☐ Punch biopsy ☐ Other (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 114a, otherwise, skip to Question 115.***
114a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
115	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
116	Metastatic/ recurrent site	☐ Bladder ☐ Bone ☐ Connective tissue ☐ Extrahepatic bile duct ☐ Gallbladder ☐ Liver ☐ Lymph node ☐ Ovary ☐ Skin ☐ Small intestine ☐ Thyroid gland ☐ Uterus ☐ Other site (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 116a, otherwise, skip to Question 117.***
116a	Other metastatic/ recurrent site	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.



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		☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva		
117	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
118	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
119	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
120	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
121	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
122	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
123	Is the patient still receiving treatment?	_____	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
124	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Additional Metastatic/Recurrent Tumor Biospecimen Information (if applicable)				
125	Are you submitting an additional metastatic/ recurrent tumor tissue sample?	☐ Yes ☐ No		A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen. ***Note: If yes, proceed to Question 126. If no, proceed to Question 142.***
126	Metastatic tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. The first biospecimen should be number "1," the second should be number "2," etc.
127	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
128	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
129	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Fresh ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
130	Number of days from index date to date of diagnosis of metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic/recurrent disease.
131	Method of metastatic/ recurrent cancer sample procurement	☐ Tumor resection ☐ Biopsy ☐ Core needle biopsy ☐ Incisional biopsy ☐ Fine needle aspiration ☐ Punch biopsy ☐ Other (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 131a, otherwise, skip to Question 132.***
131a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
132	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
133	Metastatic/ recurrent site	☐ Bladder ☐ Bone ☐ Connective tissue ☐ Extrahepatic bile duct ☐ Gallbladder ☐ Liver ☐ Lymph node ☐ Ovary ☐ Skin ☐ Small intestine ☐ Thyroid gland ☐ Uterus ☐ Other site (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 133a, otherwise, skip to Question 134.***



Enrollment: Rare

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
133a	Other metastatic/ recurrent site	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
134	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
135	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
136	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
137	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.



Enrollment: Rare

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
138	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
139	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
140	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
141	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy. ***Note: Proceed to Question 147.***
Metastatic/Recurrent Tumor Model Information				
142	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. The first biospecimen should be number "1," the second should be number "2," etc.
143	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
144	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
145	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/ RECURRENT tissue from which this model is derived.
146	Model's METASTATIC/RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived. ***Note: If submitting an additional Metastatic/Recurrent Tumor sample for model development, proceed to Question 148. Please complete the Metastatic/Recurrent Tumor Clinical Molecular Analysis Supplemental Form for each metastatic/ recurrent tumor sample collected for HCMI for this case.***



Enrollment: Rare

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Additional Metastatic/Recurrent Biospecimen Tumor Model Information (if applicable)				
147	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. The first biospecimen should be number "1," the second should be number "2," etc.
148	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
149	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
150	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/ RECURRENT tissue from which this model is derived.
151	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived. ***Note: Please complete the Metastatic/ Recurrent Tumor Clinical Molecular Analysis Supplemental Form for each metastatic/recurrent tumor sample collected for HCMI for this case.***
Other Biospecimen Information				
152	Are you submitting an OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an OTHER tissue sample (e.g. pre-malignant, non-malignant, or dysplastic tissue, etc.) was collected for HCMI for this case. ***Note: If yes, proceed to Question 153.***
153	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. The first biospecimen should be number "1," the second should be number "2," etc.
154	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
155	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
156	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Fresh ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
157	Other method of cancer sample procurement	☐ Tumor resection ☐ Biopsy ☐ Core needle biopsy ☐ Incisional biopsy ☐ Fine needle aspiration ☐ Punch biopsy ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 157a, otherwise, skip to Question 158.***
157a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.



Enrollment: Rare

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

158	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
159	Tissue type	☐ Non-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 159a, otherwise, skip to Question 160.***
159a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
160	Anatomic site of OTHER tissue	☐ Bladder ☐ Bone ☐ Connective tissue ☐ Extrahepatic bile duct ☐ Gallbladder ☐ Liver ☐ Lymph node ☐ Ovary ☐ Skin ☐ Small intestine ☐ Thyroid gland ☐ Uterus ☐ Other site (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 160a, otherwise, skip to Question 161.***
160a	Specify anatomic site of OTHER tissue	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organ ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	6584916	Specify the site of OTHER tissue, if not in the previous list.



Enrollment: Rare

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
161	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
162	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI. ***Note: Proceed to Question 163.***
Additional OTHER biospecimen Information (if applicable)				
163	Are you submitting an additional OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an additional OTHER tissue sample (pre-malignant, non-malignant, or dysplastic tissue, etc.) is being submitted for HCMI for this case. ***Note: If yes, proceed to Question 164. If no, proceed to Question 174.***
164	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
165	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
166	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
167	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Fresh ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
168	Other method of cancer sample procurement	☐ Tumor resection ☐ Biopsy ☐ Core needle biopsy ☐ Incisional biopsy ☐ Fine needle aspiration ☐ Punch biopsy ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 168a, otherwise, skip to Question 169.***
168a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
169	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue tissue submitted for HCMI.
170	Tissue type	☐ Non-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 170a, otherwise, skip to Question 171.***
170a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
171	Anatomic site of OTHER tissue	☐ Bladder ☐ Bone ☐ Connective tissue ☐ Extrahepatic bile duct ☐ Ovary ☐ Skin ☐ Small intestine ☐ Thyroid gland ☐ Uterus ☐ Other site (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 171a, otherwise, skip to Question 172.***



Enrollment: Rare

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
171a	Specify anatomic site of OTHER tissue	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperiton-eum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	6584916	Specify the site of OTHER tissue, if not in the previous list.
172	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
173	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI. ***Note: Proceed to Question 174.***
Other Tissue Model Information				
174	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
175	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
176	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
177	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
178	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.



Enrollment: Rare

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Additional Other Tissue Model Information (if applicable)				
179	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. The first biospecimen should be number "1," the second should be number "2," etc.
180	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
181	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
182	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
183	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.



Enrollment: Rare

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Metastatic/Recurrent Tumor Clinical Molecular Analysis Supplemental Form

Note: Complete a separate 'Metastatic/Recurrent Tumor Clinical Molecular Analysis Supplemental Form' for each unique metastatic and/or recurrent tumor tissue collected for model development for HCMI.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Metastatic/Recurrent Tumor Clinical Molecular Analysis Information				
1	Metastatic tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. The first biospecimen should be number "1," the second should be number "2," etc.
2	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
3	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
4	MMR status	☐ Evidence of MMR mutation by sequencing ☐ Evidence of MMR protein loss by IHC ☐ MMR loss evidence hypermutation phenotype (>10mutations/Mb) ☐ No evidence of MMR alteration	6002208	Indicate the patient's Mismatch Repair (MMR) gene mutation status.
5	MYCN gene amplification status	☐ Amplified ☐ Not amplified ☐ Not done ☐ Unknown	4616052	Indicate the amplification status of the MYCN gene.
6	MLH1 promoter methylation status	☐ MLH1 promoter hypermethylation present ☐ MLH1 promoter hypermethylation absent ☐ MLH1 promoter hypermethylation not assessed ☐ Indeterminate	6033150	Indicate the methylation status of the MLH1 promoter.
7	Was HER2 FISH/CISH performed?	☐ Yes ☐ No ☐ Unknown	6063447	Indicate whether HER2 was assessed by fluorescence in situ hybridization (FISH) or chromogenic in situ hybridization (CISH). ***Note: If yes, proceed to Questions 7a-e.***
7a	HER2 status by FISH/CISH	☐ Amplified ☐ Not amplified ☐ Equivocal	2854089	Select the HER2 status as assessed by FISH/CISH.
7b	HER2 copy number	_____	3133738	If HER2 copy number testing was performed, provide the average number of HER2 fluorescence in situ hybridization (FISH) signals for the patient's primary tumor.
7c	Centromere 17 copy number	_____	3104295	If Centromere 17 copy number testing was performed, provide the average number of Centromere 17 fluorescence in situ hybridization (FISH) signals for the patient's primary tumor.
7d	Number of cells counted for HER2 and Centromere 17 copy numbers	_____	3087902	Provide the total number of cells counted to assess HER2 and Centromere 17 copy numbers.
7e	HER2/Centromere 17 signal ratio	_____	2497552	If HER2 and Centromere 17 copy number analyses were performed by FISH, provide the ratio of the outcomes of these tests.



Enrollment: Rare

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Metastatic/Recurrent Tumor Mutational Analysis				
8	Was mutation analysis performed for any of the following genes?	☐ ALK ☐ BRAF ☐ CDKN2A ☐ EGFR ☐ GNAS ☐ H3 K27 ☐ IDH1/2 ☐ KRAS ☐ PIK3CA ☐ PTEN ☐ TP53		Select the gene(s) for which mutation analysis was performed. ***Note: If ALK is selected, proceed to Question 9; if BRAF is selected, proceed to Question 10; If CDKN2A is selected, proceed to Question 11; If EGFR is selected, proceed to Question 12; If GNAS is selected, proceed to Question 13; If H3 K27 is selected, proceed to Question 14; If IDH1/2 is selected, proceed to Question 15; If KRAS is selected, proceed to Question 16; If PIK3CA is selected, proceed to Question 17; If PTEN is selected, proceed to Question 18; If TP53 is selected, proceed to Question 19.***
9	Was a mutation in ALK identified?	☐ Yes ☐ No	3774202	Indicate whether a mutation in ALK was identified. ***Note: If yes, proceed to Question 9a.***
9a	If ALK mutation identified, which one?	☐ F1174L ☐ K1062M ☐ R1275Q ☐ T1087I ☐ F1174C ☐ F1174V ☐ F1245L ☐ Other (specify)	6060279	Select the ALK mutation identified. ***Note: If the ALK mutation is not listed, proceed to Question 9b.***
9b	Other ALK mutation	_____	6101680	If the ALK mutation identified is not included in the provided list, specify the ALK mutation identified.
10	Was a mutation in BRAF identified?	☐ Yes ☐ No	6061809	Indicate whether a mutation in BRAF was identified through mutation analysis. ***Note: If yes, proceed to Question 10.***
10a	If BRAF mutation identified, which one?	☐ V600E ☐ V600D ☐ V600K ☐ V600R ☐ K601E ☐ Other (specify)	6061810	Indicate the specific BRAF mutation identified. ***Note: If the BRAF mutation is not listed, proceed to Question 11.***
10b	Other BRAF mutation	_____	6101687	If the BRAF mutation is not included in the list provided, specify the BRAF mutation identified.
10c	What sequencing assay was used to identify the BRAF mutation?	☐ Next generation targeted sequencing ☐ Whole exome sequencing ☐ Other (specify)	6003729	Select the sequencing assay used to identify the somatic mutation. ***Note: If the sequencing assay is not listed, proceed to Questions 10d.***
10d	Other sequencing assay	_____	6002204	If the sequencing assay is not included in the provided list, specify the other sequencing assay.
11	Was a mutation in CDKN2A identified?	☐ Yes ☐ No	6063534	Indicate whether a mutation in CDKN2A was identified through mutation analysis. ***Note: If yes, proceed to question 11a.***
11a	If CDKN2A mutation identified, which one?	☐ A30V ☐ V51D ☐ V51I ☐ H83P ☐ H83Y ☐ D108H ☐ D108Y ☐ L130Q ☐ A147T ☐ A148T ☐ Other (specify)	6063732	Indicate the specific CDKN2A mutation identified. ***Note: If the CDKN2A mutation is not listed, proceed to Question 11b.***
11b	Other CDKN2A mutation(s)	_____	6101684	If the CDKN2A mutation identified is not provided in the previous list, specify the CDKN2A mutation.
12	Was a mutation in EGFR identified?	☐ Yes ☐ No	6063530	Indicate whether a mutation in EGFR was identified through mutation analysis. ***Note: If yes, proceed to Question 12a.***
12a	If EGFR mutation identified, which one?	☐ G719X ☐ T790M ☐ C797S ☐ L858R ☐ L861Q ☐ Exon 19 deletion ☐ Exon 20 insertion ☐ Other (specify)	3147627	Indicate the specific EGFR mutation identified. ***Note: If the EGFR mutation is not listed, proceed to Question 12b.***
12b	Other EGFR mutation(s)	_____	4173882	If the EGFR mutation identified is not provided in the previous list, specify the EGFR mutation.
13	Was a mutation in GNAS identified?	☐ Yes ☐ No	5983161	Indicate whether a mutation in GNAS was identified through mutation analysis. ***Note: If yes, proceed to Question 13a.***



Enrollment: Rare

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
13a	If GNAS mutation identified, which one?	☐ Q125R ☐ R160C ☐ R201C ☐ R201H ☐ R201S ☐ Q227E ☐ Q227L ☐ Q227P ☐ Q227R ☐ Other (specify)	6063733	Indicate the specific GNAS mutation identified. ***Note: If the GNAS mutation is not listed, proceed to Question 13b.***
13b	Other GNAS mutation(s)	_____	6101685	If the GNAS mutation identified is not provided in the previous list, specify the GNAS mutation.
14	Was a mutation in H3 K27 identified?	☐ Yes ☐ No	6002202	Indicate whether H3 K27 mutation was identified. ***Note: If yes, proceed to Question 14a.***
14a	If H3 K27 mutation identified, in which variant was it found?	☐ H3.1 ☐ H3.3 ☐ Other	6002205	Select the H3 K27 mutation identified.
15	Was a mutation in IDH1/2 identified?	☐ Yes ☐ No	6002200	Indicate whether an IDH1 or IDH2 mutation was identified at testing. ***Note: If yes, proceed to Question 15a.***
15a	If IDH1/2 mutation identified, which one?	☐ IDH1 R132H ☐ IDH1 R132C ☐ IDH1 R132S ☐ IDH1 R132G ☐ IDH1 R132L ☐ IDH2 R172W ☐ IDH2 R172K ☐ IDH2 R172M ☐ Other (specify)	6002206	Select the mutation identified in IDH1/2. ***Note: If the IDH1/2 mutation is not listed, proceed to Question 15b.***
15b	Other IDH1/2 mutation	☐ _____	6002207	If the mutation in IDH1/2 is not included in the provided list, specify the mutation in IDH1/2.
15c	What sequencing assay was used to identify the IDH1/2 mutation?	☐ Next generation targeted sequencing ☐ Whole exome sequencing ☐ Not performed ☐ Other (specify)	6003729	Select the sequencing assay used to identify the somatic mutation. ***Note: If the sequencing assay is not listed, proceed to Question 15d.***
15d	Other sequencing assay	☐ _____	6002204	If the sequencing assay is not included in the provided list, specify the other sequencing assay.
16	Was a mutation in KRAS identified?	☐ Yes ☐ No	6060081	Indicate whether a mutation in KRAS was identified through mutation analysis. ***Note: If yes, proceed to Question 16a.***
16a	If KRAS mutation identified, which one?	☐ G12A ☐ G12C ☐ G12D ☐ G12R ☐ G12S ☐ G12V ☐ G13A ☐ G13C ☐ G13D ☐ G13R ☐ G13V ☐ Q61H ☐ Q61L ☐ A146T ☐ Other (specify)	6060083	Indicate the specific KRAS mutation identified. ***Note: If the KRAS mutation is not listed, proceed to Question 16b.***
16b	Other KRAS mutation	☐ _____	6101691	If the KRAS mutation identified is not provided in the previous list, specify the KRAS mutation.
17	Was a mutation in PIK3CA identified?	☐ Yes ☐ No	6063524	Indicate whether a mutation in PIK3CA was identified through mutation analysis. ***Note: If yes, proceed to Question 17a.***
17a	If PIK3CA mutation identified, in what exon?	☐ 9 ☐ 20 ☐ Other (specify)	6063735	Indicate the specific exon of the PIK3CA gene in which the mutation was identified. ***Note: If the PIK3CA mutation is not listed, proceed to Question 17b.***
17b	Other PIK3CA mutation	_____	6101688	If the specific exon of the PIK3CA gene mutation abnormality identified was not included in the previous list, please specify the exon.
18	Was a mutation in PTEN identified?	☐ Yes ☐ No	6063529	Indicate whether a mutation in PTEN was identified through mutation analysis. ***Note: If yes, proceed to Question 18a.***



Enrollment: Rare

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
18a	If PTEN mutation identified, which one?	☐ Exon 1-9 mutation present ☐ Cannot be determined ☐ Other (specify	6063736	Indicate whether a mutation in exon 1-9 of PTEN was identified. ***Note: If the PIK3CA mutation is not listed, proceed to Question 18b.***
18b	Other PTEN mutation	_____	6101689	If the PTEN gene mutation identified is not in exons 1-9, please specify the exon.
19	Was a mutation in TP53 identified?	☐ Yes ☐ No	6063523	Indicate whether a mutation in TP53 was identified through mutation analysis. ***Note: If yes, proceed to Question 19a.***
19a	If TP53 mutation identified, which one?	☐ R175H ☐ R248Q ☐ R273H ☐ R213L ☐ R248W ☐ R273L ☐ Y220C ☐ G266E ☐ R282G ☐ C238Y ☐ G266V ☐ R282W ☐ G245D ☐ V272M ☐ Other (specify) ☐ G245S ☐ R273C	6063731	Indicate the specific TP53 mutation identified. ***Note: If the TP53 mutation is not listed, proceed to Question 19b.***
19b	Other TP53 mutation(s)	_____	6101683	If the TP53 mutation identified is not provided in the previous list, specify the TP53 mutation.
19c	What sequencing assay was used to identify the TP53 mutation?	☐ Next generation targeted sequencing ☐ Whole exome sequencing ☐ Not performed ☐ Other (specify)	6003729	Select the sequencing assay used to identify the somatic mutation. ***Note: If the sequencing assay is not listed, proceed to Question 19d.***
19d	Other sequencing assay	_____	6002204	If the sequencing assay is not included in the provided list, specify the other sequencing assay.
Metastatic/Recurrent Tumor Protein Expression Information				
20	Was IHC performed in any of the following proteins?	☐ BRAF V600E ☐ ER ☐ H3 K27M ☐ HER2 ☐ IDH1 R132H ☐ MLH1 ☐ MSH2 ☐ MSH6 ☐ PMS2 ☐ PD-L1 ☐ PR ☐ PTEN ☐ SMAD4		Select the protein(s) for which IHC was performed. ***Note: If BRAF V600E is selected, proceed to Question 21; If ER is selected, proceed to Question 22. If H3 K27M is selected, proceed to Question 23; If HER2 is selected, proceed to Question 24; If IDH1 R132H is selected, proceed to Question 25; If MLH1 is selected, proceed to Question 26; If MSH2 is selected, proceed to Question 27; If MSH6 is selected, proceed to Question 28; If PMS2 is selected, proceed to Question 29; If PD-L1 is selected, proceed to Question 30; If PR is selected, proceed to Question 31; If PTEN is selected, proceed to Question 32; if SMAD4 is selected, proceed to Question 33.***
21	BRAF V600E expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6428124	Indicate the expression of BRAF V600E by immunohistochemistry (IHC).
22	Estrogen Receptor (ER) Allred score	☐ 1 ☐ 4 ☐ 2 ☐ 5 ☐ 7 ☐ 3 ☐ 6	2419219	Indicate the numeric Allred score (cell staining percentage plus intensity) for estrogen receptor.
23	H3 K27M expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6002203	Indicate the expression of H3 K27M by immunohistochemistry (IHC).
24	HER2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	2957563	Indicate the expression of HER2 as assessed by immunohistochemistry (IHC).
25	IDH1 R132H expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063674	Indicate the expression of IDH1 R132H as assessed by immunohistochemistry (IHC).
26	MLH1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063668	Indicate the status of MLH1 protein expression as determined by immunohistochemistry (IHC).
27	MSH2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063669	Indicate the status of MSH2 protein expression as determined by immunohistochemistry (IHC).



Enrollment: Rare

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
28	MSH6 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063671	Indicate the status of MSH6 protein expression as determined by immunohistochemistry (IHC).
29	PMS2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063670	Indicate the status of PMS2 protein expression as determined by immunohistochemistry (IHC).
30	PD-L1 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	4798631	Indicate the status of PD-L1 protein expression as determined by immunohistochemistry (IHC).
31	Progesterone receptor (PR) expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063673	Indicate the expression of progesterone receptor as assessed by immunohistochemistry (IHC).
32	PTEN expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063672	Indicate the status of PTEN protein expression as determined by immunohistochemistry (IHC).
33	SMAD4 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063676	Indicate the status of SMAD4 protein expression as determined by immunohistochemistry (IHC).



Enrollment: Rhabdomyosarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Form Notes: An Enrollment Form should be completed for each HCMI case upon qualification notice from Leidos. All information provided on this form should include activity from the Date of Initial Pathologic Diagnosis to the most recent Date of Last Contact with the patient.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	☐ Initial pathologic diagnosis ☐ Sample procurement ☐ First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.
Patient Information				
4	Gender	☐ Male ☐ Female ☐ Unspecified	2200604	Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
5	Height	_____	649	Provide the patient's height, in centimeters.
6	Weight	_____	651	Provide the patient's weight, in kilograms.
7	Body mass index (BMI)	_____	2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
8	Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown ☐ Not reported	2192199	Provide the patient's race using the defined categories. **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 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. **Black or African American:** A person having origins in any of the black racial groups of Africa. **Native Hawaiian or other Pacific Islander:** A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island. **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.



Enrollment: Rhabdomyosarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
9	Ethnicity	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Not reported	2192217	Provide the patient's ethnicity using the defined categories. **Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. **Not Hispanic or Latino:** A person not meeting the definition of Hispanic or Latino.
10	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.
11	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. ***Note: If the patient's age is greater than 32,872 days (90 years), please enter 32,872.***
12	Year of birth	_____	2896954	Provide the year of the patient's birth. If the patient was born prior to 1928, insert the date 1928.
13	Family history of cancer	☐ Same ☐ Different ☐ None ☐ Unknown	5832923	Has a first-degree relative of the patient been diagnosed with a cancer of the same or a different type?
14	Smoking history	☐ Lifelong non-smoker (<100 cigarettes smoked in a lifetime) ☐ Current smoker (includes daily and non-daily smokers) ☐ Current reformed smoker (duration not specified) ☐ Current reformed smoker for >15 years ☐ Current reformed smoker for ≤15 years	2181650	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories.
15	Metastasis at diagnosis assessment status	☐ Metastatic ☐ Non-metastatic (confirmed) ☐ Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor. ***Note: If metastatic at diagnosis, proceed to Question 16, otherwise, skip to Question 17.***
16	Metastatic site(s) at diagnosis	☐ Lung ☐ Bone ☐ Bone marrow ☐ Lymph node(s) ☐ Lymph node(s) - distant ☐ Other (specify)	3029815	Indicate the site(s) of metastasis at the time of diagnosis of the primary tumor. ***Note: If the anatomic site of tumor tissue is not listed, proceed to Question 16a, otherwise, skip to Question 17.***
16a	Specify metastatic site(s)	_____	3128033	If the site of metastasis is not included on the provided list, specify the site of metastasis.
Biospecimen Information				
17	Tissue sample type(s) collected for HCMI for this case	☐ Normal tissue ☐ Primary tumor ☐ Metastatic ☐ Recurrent ☐ Other tissue	2006911	Please select all the tissue sample types submitted for HCMI with this case.



Enrollment: Rhabdomyosarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
18	Number of NORMAL tissues biospecimens collected for HCMI for this case	_____	6584256	Please provide the number of normal tissue specimens obtained for HCMI for this case. ***Note: This number is expected to be 1.***
19	Number of PRIMARY cancer tissue biospecimens collected for HCMI model development for this case	_____	6584257	Please provide the number of primary tumor specimens obtained for HCMI for this case. ***Note: A single primary tumor biospecimen obtained that is portioned for both sequencing and model generation counts as 1 single primary tumor specimen. This number is expected to be 1.***
20	Number of METASTATIC/RECURRENT cancer tissue biospecimens collected for HCMI model development for this case	_____	6584258	Please provide the number of metastatic and/or recurrent cancer biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
21	Number of OTHER tissue biospecimens collected for HCMI model development for this case	_____	6584259	Please provide the number of pre-malignant, non-malignant, or dysplastic tissue biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
22	Total number of tissue biospecimens collected for HCMI for this case	_____	6584271	Please provide the total number of tissue biospecimens collected for HCMI for this case. ***Note: This number should be the sum of the normal, primary tumor, metastatic/recurrent tumor, and other biospecimen counts above.***
Normal Control Information				
23	Normal tissue biospecimen ordinal	_____	6584264	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***



Enrollment: Rhabdomyosarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
24	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
25	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
26	Type of normal control	☐ Whole blood ☐ Buccal cells ☐ Buffy coat ☐ Lymphocytes ☐ Extracted DNA from blood ☐ Extracted DNA from saliva ☐ Extracted DNA from buccal cells ☐ Extracted DNA from normal tissue ☐ FFPE non-neoplastic tissue ☐ Non-neoplastic tissue	3081936	Indicate the type of normal control submitted for this case.
27	Anatomic site of normal tissue	☐ Skin ☐ Fibroadipose tissue ☐ Other (specify) ☐ Not applicable	4132152	If non-neoplastic tissue was submitted as the normal control, select the anatomic site of the normal tissue. ***Note: If the anatomic site of normal tissue is not listed, proceed to Question 27a, otherwise, skip to Question 28.***
27a	Other anatomic site of normal tissue	_____	3288189	If non-neoplastic tissue, adjacent tissue, or normal tissue from another anatomic site was submitted as the normal control, provide the anatomic site of the normal tissue.
28	Distance from tumor to normal control tissue (if not blood)	☐ Adjacent (< or = 2cm) ☐ Distal (>2cm) ☐ Unknown ☐ Not applicable	3088708	Indicate the distance from the site of normal tumor collection to the primary tumor. ***Note: If normal tissue was not submitted, select 'Not applicable'.***
29	Normal tissue sample preservation method	☐ Cryopreserved ☐ OCT ☐ FFPE ☐ Snap frozen ☐ Frozen	5432521	Provide the method used to preserve the normal tissue sample collected for molecular characterization.
Primary Tumor Biospecimen Information				
30	ICD-10 code for primary tumor	☐ C49.0 ☐ C49.1 ☐ C49.2 ☐ C49.3 ☐ C49.4 ☐ C49.5 ☐ C49.6 ☐ C49.8 ☐ C49.9 ☐ Other (specify)	3226287	Provide the ICD-10 code for the primary tumor as used to generate the ID3 for this subject. ***Note: If the ICD-10 code is not listed, proceed to 30a, otherwise, skip to Question 31.***
30a	Other ICD-10 code for primary tumor	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.



Enrollment: Rhabdomyosarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
31	Tumor Morphology	☐ 8900/3 (Rhabdomyosarcoma, NOS) ☐ 8901/3 (Pleomorphic rhabdomyosarcoma, NOS) ☐ 8902/3 (Mixed type rhabdomyosarcoma) ☐ 8910/3 (Embryonal rhabdomyosarcoma, NOS) ☐ 8912/3 (Spindle cell rhabdomyosarcoma) ☐ 8920/3 (Alveolar rhabdomyosarcoma) ☐ 8921/3 (Rhabdomyosarcoma with ganglionic differentiation) ☐ Other (specify)	3226275	Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor. ***Note: If the ICD-O-3 histology code of the primary tumor is not listed, proceed to Question 31a, otherwise, skip to Question 32.***
31a	Specify other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.
32	Tissue or organ of origin	☐ Abdominal cavity ☐ Bladder ☐ Head and neck ☐ Limb ☐ Prostate ☐ Retroperitoneum ☐ Testes ☐ Other (specify)	3427536	Using the patient's pathology/laboratory report, select the primary site of the disease. ***Note: If the primary site of the disease is not listed, proceed to Question 32a, otherwise skip to Question 33.***
32a	Other tissue or organ of origin	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	3427536	If the primary site of the disease is not included on the previous list, provide the primary site of the disease.



Enrollment: Rhabdomyosarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
33	Histological Type	☐ Rhabdomyosarcoma ☐ Other (specify)	3081932	Select the surgical pathology text description of the histological tumor type. ***Note: If the histological tumor type is not listed, proceed to Question 33a, otherwise, skip to Question 34.***
33a	Other histological type	_____	3294805	If the traditional surgical pathology text description of the histological tumor type is not included on the previous list, please specify the histological type.
34	Histological subtype	☐ Alveolar ☐ Embryonal ☐ Other ☐ Unknown	5153032	Using the patient's pathology/laboratory report, select the histological subtype of the primary tumor.
35	Prior malignancy (of the same cancer type)	☐ Yes ☐ No ☐ Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
36	Prior malignancy (other cancer type)	☐ Yes ☐ No ☐ Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.
37	Tumor stage	☐ 1: Favorable site ☐ 2: Unfavorable site; <= 5cm; no regional node involvement ☐ 3: Unfavorable site; > 5 cm; and/or regional node involvement ☐ 4: Metastatic disease	5162089	Provide the stage of the tumor using the IRS (Intergroup Rhabdomyosarcoma Study) staging guidelines.
38	Intergroup Rhabdomyo-sarcoma Study group	☐ I: Tumor completely removed ☐ IIa: Microscopic residual; margin positive; nodes negative ☐ IIb: Microscopic residual; margin negative; nodes positive (completely resected) ☐ IIc: Microscopic residual; margin positive; nodes positive (completely resected) ☐ III: Gross residual ☐ IV: Metastasis ☐ Unknown	4925522	Indicate the post-surgical procedure neoplasm status by IRS group.
39	Children's Oncology Group risk group	☐ High ☐ Low ☐ Intermediate ☐ Unknown	2963688	Indicate the soft-tissue sarcoma histologic grade.
40	Was tumor confined to organ of origin?	☐ Yes ☐ No ☐ Unknown ☐ Not applicable	4925494	Indicate whether the tumor was confined to the organ of origin. If T1 (confined to anatomic site of origin), please select "Yes." If T2 (extension and/or fixative to surrounding tissue), please select "No."
41	Anaplasia	☐ Absent ☐ Focal ☐ Diffuse ☐ Unknown	4925534	Indicate whether anaplasia was present in the primary tumor.
42	Maximum diameter (cm) of primary tumor if identifiable at initial diagnosis	_____	62602	Provide the length of the largest diameter of the primary tumor, in centimeters.



Enrollment: Rhabdomyosarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
43	FOXO1 fusion result	☐ FOXO1 rearranged (FOXO1 with unknown partner) ☐ PAX3 – FOXO1 translocation ☐ PAX7 – FOXO1 translocation ☐ Other FOXO1 translocation (FOXO1 with known partner) ☐ No FOXO1 rearrangement ☐ Indeterminate	5159111	If the histologic subtype of the primary tumor is alveolar, select the FOXO1 gene fusion, if identified.
Primary Tumor Sample Information				
44	Are you submitting a primary tumor tissue sample for this case?	☐ Yes ☐ No		***If yes, proceed to question 45. If submitting a metastatic/recurrent tumor sample, proceed to Question 71.***
45	Primary tumor biospecimen ordinal	_____	6584265	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number should be "1".***
46	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
47	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
48	Sample represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this primary tumor specimen represent the PRIMARY DIAGNOSIS for this Case ID3? ***Note: If no, continue to Question 49, otherwise, skip to Question 50.***
49	Specify the ICD-10 code	_____	3226287	Provide the ICD-10 code for the primary tumor used to generate the model submitted to HCMI.
50	Tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the tumor tissue sample collected for molecular characterization.
51	Anatomic Site of tumor from which Model was Derived	☐ Abdominal cavity ☐ Ascites ☐ Biliary tract/liver ☐ Bladder ☐ Bone ☐ Bone marrow ☐ Head and neck (non-PM) ☐ Limb ☐ Lung ☐ Lymph node ☐ Orbit ☐ Parameningeal ☐ Pleura ☐ Prostate ☐ Retroperitoneum ☐ Testis ☐ Other (specify)	4214629	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI. ***Note: If the tissue or organ of origin is not listed, proceed to Question 51a. Otherwise, skip to Question 52.***
51a	Other anatomic site from which the tumor was obtained	_____	5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.



Enrollment: Rhabdomyosarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
52	Method of cancer sample procurement	☐ Core needle biopsy ☐ Excisional biopsy ☐ Fine needle aspiration ☐ Incisional biopsy ☐ Tumor resection ☐ Other (specify)	3103514	Provide the procedure performed to obtain the primary tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 52a, otherwise, skip to Question 53.***
52a	Specify the other method of tumor sample procurement	_____	2006730	Specify the procedure performed to obtain the primary tumor tissue, if not included in the previous list.
53	Number of days from index date to date of tumor sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the tumor tissue submitted for HCMI.
54	Tumor tissue type	☐ Primary ☐ Additional Primary ☐ NOS	3288124	Provide the primary tumor tissue type for this sample.
Primary Tumor Model Information				
55	Primary model biospecimen ordinal	_____	6594596	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number is expected to be "1".***
56	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
57	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
58	Model represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this MODEL represent the PRIMARY DIAGNOSIS for this Case ID3?
59	Model's primary tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the PRIMARY TUMOR TISSUE from which this model is derived.
60	Model's primary tumor biospecimen ordinal	_____	6584265	Enter the biospecimen ordinal of the PRIMARY TUMOR TISSUE from which this model is derived.
Treatment Information				
61	History of neoadjuvant treatment	☐ No ☐ Yes; radiation prior to resection ☐ Yes; pharmaceutical treatment prior to resection ☐ Yes; both radiation and pharmaceutical treatment prior to resection ☐ Unknown	3382737	Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment. ***Note: Pharmaceutical therapy is addressed in Questions 63-68. Radiation therapy is addressed in Questions 69-70.***
62	Neoadjuvant chemotherapy type	☐ Cytotoxic chemotherapy ☐ Hormonal ☐ Immunotherapy (cellular and immune checkpoint) ☐ Targeted therapy (small molecule inhibitors and targeted antibodies) ☐ Not applicable	5832928	Select all neoadjuvant chemotherapy types that were administered to the patient. ***Note: Cytotoxic chemotherapy is addressed in Questions 63-64. Immunotherapy is addressed in Questions 65-66. Targeted therapy is addressed in Questions 67-68.***



Enrollment: Rhabdomyosarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
63	Neoadjuvant chemotherapeutic regimen	☐ Doxorubicin ☐ Ifosfamide and Etoposide ☐ Irinotecan ☐ Temozolomide ☐ Vincristine ☐ Vinorelbine ☐ Vincristine, actinomycin-D, cyclophosphamide (VAC) ☐ Vincristine, doxorubicin, cyclophosphamide, ifosfamide, etoposide (VDC/IE) ☐ Vincristine, actinomycin-D, cyclophosphamide, vincristine, irinotecan (VAC/VI) ☐ Ifosfamide, carboplatin, etoposide (ICE) ☐ Vincristine, irinotecan, temozolomide (VIT) ☐ High-dose methotrexate, doxorubicin, cisplatin (MAP) ☐ Other (specify) ☐ Chemotherapy not given	2853313	Select all chemotherapeutics used for neoadjuvant therapy. ***Note: If neoadjuvant chemotherapy was not given, skip to Question 65. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 63a, otherwise, skip to Question 64.***
63a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapies administered.
64	Days to neoadjuvant chemotherapy treatment from index date	_____	5102411	Provide the number of days from index date to the date of treatment with neoadjuvant chemotherapy.
65	Immunotherapy name, specify	_____	2185614	Specify the name of the immunotherapy administered. ***Note: If immunotherapy was not given, skip to Question 67.***
66	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
67	Targeted Therapy	☐ Temsirolimus ☐ Other (specify)	6005154	Select the targeted therapy administered to the patient. ***Note: If targeted therapy was not given, skip to Question 69. If the targeted therapy is not listed, proceed to Question 67a, otherwise, skip to Question 68.***
67a	Specify targeted therapy	_____	4308476	Provide the name of the targeted therapy administered to the patient.
68	Days to targeted therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with targeted therapy.
69	Radiation therapy administered type	☐ 2D conventional ☐ 3D conformal ☐ Brachytherapy HDR ☐ Brachytherapy LDR ☐ IMRT ☐ Proton Beam ☐ Stereotactic Body RT ☐ Stereotactic Radiosurgery ☐ WBRT ☐ Other (specify) ☐ Unspecified ☐ Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. ***Note: If radiation therapy was not administered, proceed to Question 71. If the radiation therapy is not listed, proceed to Question 69a, otherwise, skip to Question 70.***
69a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.



Enrollment: Rhabdomyosarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
70	Days to radiation treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with radiation therapy.
Metastatic/Recurrent Tumor Biospecimen Information				
71	Are you submitting a metastatic/recurrent tumor tissue sample?	☐ Yes ☐ No		Indicate whether a metastatic/ recurrent tumor biospecimen was collected for this ID3 case. ***Note: If yes, proceed to Question 72. If submitting an OTHER tissue sample, proceed to Question 129.***
72	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1", the second should be number "2", etc.***
73	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
74	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
75	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
76	Number of days from index date to date of diagnosis of metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic/recurrent disease.
77	Method of metastatic/ recurrent cancer sample procurement	☐ Core needle biopsy ☐ Excisional biopsy ☐ Fine needle aspiration ☐ Incisional biopsy ☐ Tumor resection ☐ Other (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 77a, otherwise, skip to Question 78.***
77a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
78	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
79	Metastatic/recurrent site	☐ Abdominal cavity ☐ Ascites ☐ Biliary tract/liver ☐ Bladder ☐ Bone ☐ Head and neck (non-PM) ☐ Pleura ☐ Prostate ☐ Retroperitoneum ☐ Testis ☐ Lung ☐ Bone ☐ Bone marrow	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 79a, otherwise, skip to Question 80.***



Enrollment: Rhabdomyosarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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		☐ Limb ☐ Lymph node ☐ Orbit ☐ Parameningeal ☐ Lymph node(s) ☐ Lymph node(s) - distant ☐ Other (specify)		
79a	Other metastatic/ recurrent site	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
80	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
81	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
82	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
83	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.



Enrollment: Rhabdomyosarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
84	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
85	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
86	Is the patient still receiving treatment?	_____	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
87	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
88	Tumor stage	☐ 1: Favorable site ☐ 2: Unfavorable site; <= 5cm; no regional node involvement ☐ 3: Unfavorable site; > 5 cm; and/or regional node involvement ☐ 4: Metastatic disease	5162089	Provide the stage of the tumor using the IRS (Intergroup Rhabdomyosarcoma Study) staging guidelines.
89	Intergroup Rhabdomyo-sarcoma Study group	☐ I: Tumor completely removed ☐ IIa: Microscopic residual; margin positive; nodes negative ☐ IIb: Microscopic residual; margin negative; nodes positive (completely resected) ☐ IIc: Microscopic residual; margin positive; nodes positive (completely resected) ☐ III: Gross residual ☐ IV: Metastasis ☐ Unknown	4925522	Indicate the post-surgical procedure neoplasm status by IRS group.
90	Children's Oncology Group risk group	☐ High ☐ Low ☐ Intermediate ☐ Unknown	2963688	Indicate the soft-tissue sarcoma histologic grade.
91	Was tumor confined to organ of origin?	☐ Yes ☐ No ☐ Unknown ☐ Not applicable	4925494	Indicate whether the tumor was confined to the organ of origin. If T1 (confined to anatomic site of origin), please select "Yes." If T2 (extension and/or fixative to surrounding tissue), please select "No."
92	Anaplasia	☐ Absent ☐ Focal ☐ Diffuse ☐ Unknown	4925534	Indicate whether anaplasia was present in the primary tumor.
93	Maximum diameter (cm) of primary tumor if identifiable at initial diagnosis	_____	62602	Provide the length of the largest diameter of the primary tumor, in centimeters.
94	FOXO1 fusion result	☐ FOXO1 rearranged (FOXO1 with unknown partner) ☐ PAX3 – FOXO1 translocation ☐ PAX7 – FOXO1 translocation ☐ Other FOXO1 translocation (FOXO1 with known partner) ☐ No FOXO1 rearrangement ☐ Indeterminate	5159111	If the histologic subtype of the primary tumor is alveolar, select the FOXO1 gene fusion, if identified.



Enrollment: Rhabdomyosarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Additional Metastatic/Recurrent Tumor Biospecimen Information (if applicable)				
95	Are you submitting an additional metastatic/ recurrent tumor tissue sample?	☐ Yes ☐ No		A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen. ***Note: If yes, proceed to Question 96, otherwise, skip to Question 119.***
96	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. The first biospecimen should be number "1," the second should be number "2," etc.
97	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
98	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
99	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/ recurrent tumor tissue sample collected for molecular characterization.
100	Number of days from index date to date of diagnosis of additional metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of additional metastatic/recurrent disease.
101	Method of metastatic/ recurrent cancer sample procurement	☐ Core needle biopsy ☐ Excisional biopsy ☐ Fine needle aspiration ☐ Incisional biopsy ☐ Tumor resection ☐ Other (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 101a, otherwise, skip to Question 102.***
101a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
102	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
103	Metastatic/ recurrent site	☐ Abdominal cavity ☐ Ascites ☐ Biliary tract/liver ☐ Bladder ☐ Bone ☐ Head and neck (non-PM) ☐ Limb ☐ Orbit ☐ Parameningeal ☐ Pleura ☐ Prostate ☐ Retroperitoneum ☐ Testis ☐ Lung ☐ Bone ☐ Bone marrow ☐ Lymph node(s) ☐ Lymph node(s) - distant ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 103a, otherwise, skip to Question 104.***
103a	Other metastatic/ recurrent site	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
104	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
105	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
106	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.



Enrollment: Rhabdomyosarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
107	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
108	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
109	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
110	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
111	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
112	Tumor stage	☐ 1: Favorable site ☐ 2: Unfavorable site; <= 5cm; no regional node involvement ☐ 3: Unfavorable site; > 5 cm; and/or regional node involvement ☐ 4: Metastatic disease	5162089	Provide the stage of the tumor using the IRS (Intergroup Rhabdomyosarcoma Study) staging guidelines.
113	Intergroup Rhabdomyo-sarcoma Study group	☐ I: Tumor completely removed ☐ IIa: Microscopic residual; margin positive; nodes negative ☐ IIb: Microscopic residual; margin negative; nodes positive (completely resected) ☐ IIc: Microscopic residual; margin positive; nodes positive (completely resected) ☐ III: Gross residual ☐ IV: Metastasis Unknown	4925522	Indicate the post-surgical procedure neoplasm status by IRS group.
114	Children's Oncology Group risk group	☐ High ☐ Intermediate ☐ Low ☐ Unknown	2963688	Indicate the soft-tissue sarcoma histologic grade.
115	Was tumor confined to organ of origin?	☐ Yes ☐ No ☐ Unknown ☐ Not applicable	4925494	Indicate whether the tumor was confined to the organ of origin. If T1 (confined to anatomic site of origin), please select "Yes." If T2 (extension and/or fixative to surrounding tissue), please select "No."
116	Anaplasia	☐ Absent ☐ Focal ☐ Diffuse ☐ Unknown	4925534	Indicate whether anaplasia was present in the primary tumor.
117	Maximum diameter (cm) of primary tumor if identifiable at initial diagnosis	_____	62602	Provide the length of the largest diameter of the primary tumor, in centimeters.



Enrollment: Rhabdomyosarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
118	FOXO1 fusion result	☐ FOXO1 rearranged (FOXO1 with unknown partner) ☐ PAX3 – FOXO1 translocation ☐ PAX7 – FOXO1 translocation ☐ Other FOXO1 translocation (FOXO1 with known partner) ☐ No FOXO1 rearrangement ☐ Indeterminate	5159111	If the histologic subtype of the primary tumor is alveolar, select the FOXO1 gene fusion, if identified.
Metastatic/Recurrent Tumor Model Information				
119	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
120	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
121	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
122	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
123	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Additional Metastatic/Recurrent Biospecimen Tumor Model Information (if applicable)				
124	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
125	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
126	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
127	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
128	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.



Enrollment: Rhabdomyosarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Other Biospecimen Information				
129	Are you submitting an OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an OTHER tissue sample (e.g. pre-malignant, non-malignant, or dysplastic tissue, etc.) was collected for HCMI for this case. ***Note: If yes, proceed to Question 130.***
130	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
131	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
132	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
133	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
134	Other method of cancer sample procurement	☐ Core needle biopsy ☐ Excisional biopsy ☐ Fine needle aspiration ☐ Incisional biopsy ☐ Tumor resection ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 134a, otherwise, skip to Question 135***
134a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
135	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
136	Tissue type	☐ Non-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 136a, otherwise, skip to Question 137.***
136a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
137	Anatomic site of OTHER tissue	☐ Abdominal cavity ☐ Ascites ☐ Biliary tract/liver ☐ Bladder ☐ Bone ☐ Bone marrow ☐ Head and neck (non-PM) ☐ Limb ☐ Lung ☐ Lymph node ☐ Orbit ☐ Parameningeal ☐ Pleura ☐ Prostate ☐ Retroperitoneum ☐ Testis ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 137a, otherwise, skip to Question 138.***



Enrollment: Rhabdomyosarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
137a	Specify anatomic site of OTHER tissue	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	6584916	Specify the site of OTHER tissue, if not in the previous list.
138	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
139	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Additional OTHER biospecimen Information (if applicable)				
140	Are you submitting an additional OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an additional OTHER tissue sample (pre-malignant, non-malignant, or dysplastic tissue, etc.) is being submitted for HCMI for this case. ***Note: If yes, proceed to Question 141. If no, proceed to Question 151.***
141	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. The first biospecimen should be number "1," the second should be number "2," etc.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
142	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
143	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
144	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
145	Other method of cancer sample procurement	☐ Core needle biopsy ☐ Excisional biopsy ☐ Fine needle aspiration ☐ Incisional biopsy ☐ Tumor resection ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 145a, otherwise, skip to Question 146.***
145a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
146	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
147	Tissue type	☐ Non-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 147a, otherwise, skip to Question 148.***
147a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
148	Anatomic site of OTHER tissue	☐ Abdominal cavity ☐ Ascites ☐ Biliary tract/liver ☐ Bladder ☐ Bone ☐ Bone marrow ☐ Head and neck (non-PM) ☐ Limb ☐ Lung ☐ Lymph node ☐ Orbit ☐ Parameningeal ☐ Pleura ☐ Prostate ☐ Retroperitoneum ☐ Testis ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 148a, otherwise, skip to Question 149.***
148a	Specify anatomic site of OTHER tissue	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland	6584916	Specify the site of OTHER tissue, if not in the previous list.



Enrollment: Rhabdomyosarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

		☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva		
149	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
150	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Other Tissue Model Information				
151	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
152	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
153	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
154	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
155	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.
Additional Other Tissue Model Information (if applicable)				
156	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***



Enrollment: Rhabdomyosarcoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
157	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
158	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
159	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
160	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.



Enrollment: Stomach

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Form Notes: An Enrollment Form should be completed for each HCMI case upon qualification notice from Leidos. All information provided on this form should include activity from the Date of Initial Pathologic Diagnosis to the most recent Date of Last Contact with the patient.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	☐ Initial pathologic diagnosis ☐ Sample procurement ☐ First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.
Patient Information				
4	Gender	☐ Male ☐ Female ☐ Unspecified	2200604	Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
5	Height	_____	649	Provide the patient's height, in centimeters.
6	Weight	_____	651	Provide the patient's weight, in kilograms.
7	Body mass index (BMI)	_____	2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
8	Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown ☐ Not reported	2192199	Provide the patient's race using the defined categories. **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 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. **Black or African American:** A person having origins in any of the black racial groups of Africa. **Native Hawaiian or other Pacific Islander:** A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island. **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.



Enrollment: Stomach

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
9	Ethnicity	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Not reported	2192217	Provide the patient's ethnicity using the defined categories. **Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. **Not Hispanic or Latino:** A person not meeting the definition of Hispanic or Latino.
10	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.
11	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. ***Note: If the patient's age is greater than 32,872 days (90 years), please enter 32,872.***
12	Year of birth	_____	2896954	Provide the year of the patient's birth. If the patient was born prior to 1928, insert the date 1928.
13	Family history of cancer	☐ Same ☐ Different ☐ None ☐ Unknown	5832923	Has a first-degree relative of the patient been diagnosed with a cancer of the same or a different type?
14	Smoking history	☐ Lifelong non-smoker (<100 cigarettes smoked in a lifetime) ☐ Current smoker (includes daily and non-daily smokers) ☐ Current reformed smoker (duration not specified) ☐ Current reformed smoker for >15 years ☐ Current reformed smoker for ≤15 years	2181650	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories.
15	Metastasis at diagnosis assessment status	☐ Metastatic ☐ Non-metastatic (confirmed) ☐ Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor. ***Note: If metastatic at diagnosis, proceed to Question 16, otherwise, skip to Question 17.***
16	Metastatic site(s) at diagnosis	☐ Ascites ☐ Liver ☐ Lung ☐ Non-regional/distant lymph nodes ☐ Peritoneal surfaces ☐ Pleural effusion ☐ Other (specify)	3029815	Indicate the site(s) of metastasis at the time of diagnosis of the primary tumor. ***Note: If the anatomic site of tumor tissue is not listed, proceed to Question 16a, otherwise, skip to Question 17.***
16a	Specify metastatic site(s)	_____	3128033	If the site of metastasis is not included on the provided list, specify the site of metastasis.
Biospecimen Information				
17	Tissue sample type(s) collected for HCMI for this case	☐ Normal tissue ☐ Primary tumor ☐ Metastatic ☐ Recurrent ☐ Other tissue	2006911	Please select all the tissue sample types submitted for HCMI with this case.



Enrollment: Stomach

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
18	Number of NORMAL tissues biospecimens collected for HCMI for this case	_____	6584256	Please provide the number of normal tissue specimens obtained for HCMI for this case. ***Note: This number is expected to be 1.***
19	Number of PRIMARY cancer tissue biospecimens collected for HCMI model development for this case	_____	6584257	Please provide the number of primary tumor specimens obtained for HCMI for this case. ***Note: A single primary tumor biospecimen obtained that is portioned for both sequencing and model generation counts as 1 single primary tumor specimen. This number is expected to be 1.***
20	Number of METASTATIC/RECURRENT cancer tissue biospecimens collected for HCMI model development for this case	_____	6584258	Please provide the number of metastatic and/or recurrent cancer biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
21	Number of OTHER tissue biospecimens collected for HCMI model development for this case	_____	6584259	Please provide the number of pre-malignant, non-malignant, or dysplastic tissue biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
22	Total number of tissue biospecimens collected for HCMI for this case	_____	6584271	Please provide the total number of tissue biospecimens collected for HCMI for this case. ***Note: This number should be the sum of the normal, primary tumor, metastatic/recurrent tumor, and other biospecimen counts above.***
Normal Control Information				
23	Normal tissue biospecimen ordinal	_____	6584264	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***



Enrollment: Stomach

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
24	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
25	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
26	Type of normal control	☐ Whole blood ☐ Buccal cells ☐ Buffy coat ☐ Lymphocytes ☐ Extracted DNA from blood ☐ Extracted DNA from saliva ☐ Extracted DNA from buccal cells ☐ Extracted DNA from normal tissue ☐ FFPE non-neoplastic tissue ☐ Non-neoplastic tissue	3081936	Indicate the type of normal control submitted for this case.
27	Anatomic site of normal tissue	☐ Skin ☐ Stomach ☐ Other (specify) ☐ Not applicable	4132152	If non-neoplastic tissue was submitted as the normal control, select the anatomic site of the normal tissue. ***Note: If the anatomic site of normal tissue is not listed, proceed to Question 27a, otherwise, skip to Question 28.***
27a	Other anatomic site of normal tissue	_____	3288189	If non-neoplastic tissue, adjacent tissue, or normal tissue from another anatomic site was submitted as the normal control, provide the anatomic site of the normal tissue.
28	Distance from tumor to normal control tissue (if not blood)	☐ Adjacent (< or = 2cm) ☐ Distal (>2cm) ☐ Unknown ☐ Not applicable	3088708	Indicate the distance from the site of normal tumor collection to the primary tumor. ***Note: If normal tissue was not submitted, select 'Not applicable'.***
29	Normal tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the normal tissue sample collected for molecular characterization.
Primary Tumor Biospecimen Information				
30	ICD-10 code for primary tumor	☐ C16.0 ☐ C16.1 ☐ C16.2 ☐ C16.3 ☐ C16.4 ☐ C16.5 ☐ C16.6 ☐ C16.8 ☐ C16.9 ☐ C77.9 ☐ C78.0 ☐ C78.2 ☐ C78.6 ☐ C78.7 ☐ Other (specify)	3226287	Provide the ICD-10 code for the primary tumor as used to generate the ID3 for this subject. ***Note: If the ICD-10 code is not listed, proceed to 30a, otherwise, skip to Question 31.***
30a	Other ICD-10 code for primary tumor	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.



Enrollment: Stomach

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
31	Tumor Morphology	☐ 8020/3 ☐ 8070/3 ☐ 8140/3 ☐ 8211/3 ☐ 8255/3 ☐ 8260/3 ☐ 8480/3 ☐ 8512/3 ☐ 8560/3 ☐ 8576/3 ☐ Other (specify)	3226275	Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor. ***Note: If the ICD-O-3 histology code of the primary tumor is not listed, proceed to Question 31a, otherwise, skip to Question 32.***
31a	Specify other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.
32	Tissue or organ of origin	☐ Stomach ☐ Other (specify)	3427536	Using the patient's pathology/laboratory report, select the primary site of the disease. ***Note: If the primary site of the disease is not listed, proceed to Question 32a, otherwise skip to Question 33.***
32a	Other tissue or organ of origin	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	3427536	If the primary site of the disease is not included on the previous list, provide the primary site of the disease.



Enrollment: Stomach

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
33	Histological Type	☐ Stomach cancer ☐ Other (specify)	3081932	Select the surgical pathology text description of the histological tumor type. ***Note: If the histological tumor type is not listed, proceed to Question 33a, otherwise, skip to Question 34.***
33a	Other histological type	_____	3294805	If the traditional surgical pathology text description of the histological tumor type is not included on the previous list, please specify the histological type.
34	Histological subtype	☐ Adenosquamous carcinoma ☐ Carcinoma with lymphoid stroma (medullary carcinoma) ☐ Hepatoid adenocarcinoma ☐ Large cell neuroendocrine carcinoma ☐ Mixed adenoneuroendocrine carcinoma ☐ Neuroendocrine carcinoma (poorly differentiated) ☐ Small cell neuroendocrine carcinoma ☐ Squamous cell carcinoma ☐ Tubular (intestinal) adenocarcinoma ☐ Undifferentiated carcinoma ☐ Other (specify) ☐ Unknown	5153032	Using the patient's pathology/laboratory report, select the histological subtype of the primary tumor. ***Note: If the histological subtype is not listed, proceed to Question 34a, otherwise, skip to Question 35. If the histological subtype is Tubular (intestinal) adenocarcinoma, proceed to Question 35, otherwise, skip to Question 36.***
34a	Other histological subtype	_____	3124492	If the histological subtype for the primary tumor is not included in the provided list, specify the histological subtype.
35	If tubular (intestinal) adenocarcinoma, what is the subclassification?	☐ Mucinous adenocarcinoma (>50% mucinous) ☐ Mixed carcinoma ☐ Papillary adenocarcinoma ☐ Poorly cohesive carcinoma (including signet-ring cell carcinoma and other variants) ☐ Unknown	6270564	If the histological subtype of the primary tumor is tubular (intestinal) adenocarcinoma, provide the subclassification.
36	Prior malignancy (of the same cancer type)	☐ Yes ☐ No ☐ Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
37	Prior malignancy (other cancer type)	☐ Yes ☐ No ☐ Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.
38	AJCC cancer staging edition	☐ 1st ☐ 2nd ☐ 3rd ☐ 4th ☐ 5th ☐ 6th ☐ 7th ☐ 8th	2722309	Select the AJCC staging handbook edition used to stage the patient.
39	Clinical stage group	☐ Stage 0 ☐ Stage I ☐ Stage IA ☐ Stage IB ☐ Stage IIA ☐ Stage IIB ☐ Stage III ☐ Stage IIIA ☐ Stage IIIB ☐ Stage IIIC ☐ Stage IV ☐ Stage IVA ☐ Stage IVB	3440332	Using the patient's pathology/laboratory report, select the clinical stage group of the primary tumor as defined by the American Joint Committee on Cancer (AJCC).
40	Pathologic spread: Primary tumor (pT)	☐ T0 ☐ Tis ☐ T1 ☐ T1a ☐ T1b ☐ T2 ☐ T3 ☐ T4 ☐ T4a ☐ T4b ☐ TX	3045435	Using the patient's pathology/laboratory report, select the code for the pathologic T (primary tumor) as defined by the American Joint Committee on Cancer (AJCC).



Enrollment: Stomach

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
41	Pathologic spread: Lymph nodes (pN)	☐ N0 ☐ N1 ☐ N2 ☐ N3 ☐ N3a ☐ N3b ☐ NX	3203106	Using the patient's pathology/ laboratory report, select the code for the pathologic N (nodal) as defined by the American Joint Committee on Cancer (AJCC).
42	Pathologic spread: Distant metastases (pM)	☐ M0 ☐ M1	3045439	Using the patient's pathology/ laboratory report, select the code for the pathologic M (metastasis) as defined by the American Joint Committee on Cancer (AJCC).
43	Tumor stage (pathological)	☐ Stage 0 ☐ Stage IA ☐ Stage IB ☐ Stage IIA ☐ Stage IIB ☐ Stage IIIA ☐ Stage IIIB ☐ Stage IIIC ☐ Stage IV	3203222	Using the patient's pathology/laboratory report, in conjunction with the patient's medical record, select the stage as defined by the American Joint Committee on Cancer (AJCC).
44	Tumor grade	☐ G1-Well differentiated ☐ G2-Moderately differentiated ☐ G3-Poorly differentiated ☐ G4-Undifferentiated ☐ GB-Borderline histologic grade ☐ GX-Unknown	2785839	Using the patient's pathology/ laboratory report, select the grade of the primary tumor.
Prognostic/Predictive/Lifestyle Features for Primary Tumor Prognosis or Responsiveness to Treatment				
45	Patient history of reflux disease	☐ Yes ☐ No ☐ Unknown	3203079	Indicate whether the patient has a history of reflux disease. ***Note: If the patient does not have a history of reflux disease, skip to Question 48.***
46	Was the patient receiving anti-reflux treatment at the time of sample procurement?	☐ Yes ☐ No ☐ Unknown	3203107	Indicate whether the patient was on an anti-reflux treatment at the time of cancer sample procurement for HCMI. ***Note: If the patient was not receiving anti-reflux treatment at the time of sample procurement, skip to Question 48.***
47	If the patient was receiving anti-reflux treatment at the time of sample procurement, what treatment was being given?	☐ Antacids (e.g. Tums/Ca2+/Gaviscon/Bismuth/etc.) ☐ H2 blockers (e.g. Zantac/Tagamet/etc.) ☐ Proton pump inhibitors (e.g. Prilosec/Nexium/etc.) ☐ Unknown	3203127	Indicate the type of anti-reflux treatment given to the patient at the time of cancer sample procurement.
48	Previous or current diagnosis of Barrett's Esophagus	☐ Yes ☐ No ☐ Unknown	3203140	Indicate whether the patient had a previous or has a current diagnosis of Barrett's esophagus.
49	Previous or current diagnosis of H. pylori infection?	☐ Previous ☐ Current ☐ Never ☐ Unknown	3440211	Indicate whether the patient was diagnosed with Helicobacter pylori infection.
50	Additional pathologic findings	☐ Intestinal metaplasia ☐ Low-grade dysplasia ☐ High-grade dysplasia ☐ Helicobacter pylori-type gastritis ☐ Autoimmune atrophic chronic gastritis ☐ Polyp(s) ☐ None identified	6270578	Indicate other significant pathological findings.



Enrollment: Stomach

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
51	Lymphovascular invasion present?	☐ Yes ☐ No ☐ Unknown	64727	Indicate whether large vessel (vascular) or small, thin-walled (lymphatic) invasion was detected in the tumor specimen.
52	Perineural invasion present?	☐ Yes ☐ No ☐ Unknown	64181	Indicate whether perineural invasion or infiltration is present.
53	Was HER2 IHC performed?	☐ Yes ☐ No ☐ Unknown	6063454	Indicate whether HER2 expression was assessed by immunohistochemistry (IHC). ***Note: If HER2 IHC was not performed, skip to Question 55.***
54	HER2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	2957563	Indicate the expression of HER2 as assessed by immunohistochemistry (IHC).
55	Was HER2 CISH/FISH performed?	☐ Yes ☐ No ☐ Unknown	6063447	Indicate whether HER2 was assessed by fluorescence in situ hybridization (FISH) or chromogenic in situ hybridization (CISH). ***Note: If HER2 FISH/CISH was not performed, skip to Question 61.***
56	HER2 status by FISH/CISH	☐ Amplified ☐ Not amplified ☐ Equivocal	2854089	Select the HER2 status as assessed by FISH/CISH.
57	HER2 copy number	_____	3133738	If HER2 copy number testing was performed, provide the average number of HER2 fluorescence in situ hybridization (FISH) signals for the patient's primary tumor.
58	Centromere 17 copy number	_____	3104295	If Centromere 17 copy number testing was performed, provide the average number of Centromere 17 fluorescence in situ hybridization (FISH) signals for the patient's primary tumor.
59	Number of cells counted for HER2 and Centromere 17 copy numbers	_____	3087902	Provide the total number of cells counted to assess HER2 and Centromere 17 copy numbers.
60	HER2/Centromere 17 signal ratio	_____	2497552	If HER2 and Centromere 17 copy number analyses were performed by FISH, provide the ratio of the outcomes of these tests.
61	Tumor regression grade	☐ 0 (Complete response) ☐ 1 (Near complete response) ☐ 2 (Partial response) ☐ 3 (Poor or no response) ☐ Not assessed	6471217	Select the tumor regression grade that represents the histological response to neoadjuvant therapy.



Enrollment: Stomach

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Primary Tumor Sample Information				
62	Are you submitting a primary tumor tissue sample for this case?	☐ Yes ☐ No		***If yes, proceed to question 63. If submitting a metastatic/recurrent tumor sample, proceed to Question 89.***
63	Primary tumor biospecimen ordinal	_____	6584265	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number should be "1".***
64	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
65	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
66	Sample represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this primary tumor specimen represent the PRIMARY DIAGNOSIS for this Case ID3? ***Note: If no, continue to Question 67 otherwise, skip to Question 68.***
67	Specify the ICD-10 code	_____	3226287	Provide the ICD-10 code for the primary tumor used to generate the model submitted to HCMI.
68	Tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the tumor tissue sample collected for molecular characterization.
69	Anatomic Site of tumor from which Model was Derived	☐ Stomach – antrum ☐ Stomach – body ☐ Stomach – fundus ☐ Gastroesophageal junction ☐ Pylorus ☐ Stomach (NOS) ☐ Ascites ☐ Liver ☐ Lung ☐ Lymph node ☐ Other (specify)	4214629	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI. ***Note: If the tissue or organ of origin is not listed, proceed to Question 69a. Otherwise, skip to Question 70.***
69a	Other anatomic site from which the tumor was obtained	_____	5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.
70	Method of cancer sample procurement	☐ Biopsy ☐ Fine needle aspiration ☐ Fluid drainage ☐ Surgical resection ☐ Other (specify)	3103514	Provide the procedure performed to obtain the primary tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 70a, otherwise, skip to Question 71.***
70a	Specify the other method of tumor sample procurement	_____	2006730	Specify the procedure performed to obtain the primary tumor tissue, if not included in the previous list.
71	Number of days from index date to date of tumor sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the tumor tissue submitted for HCMI.



Enrollment: Stomach

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
72	Tumor tissue type	☐ Primary ☐ Additional Primary ☐ NOS	3288124	Provide the primary tumor tissue type for this sample.
Primary Tumor Model Information				
73	Primary model biospecimen ordinal	_____	6594596	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number is expected to be "1".***
74	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
75	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
76	Model represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this MODEL represent the PRIMARY DIAGNOSIS for this Case ID3?
77	Model's primary tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the PRIMARY TUMOR TISSUE from which this model is derived.
78	Model's primary tumor biospecimen ordinal	_____	6584265	Enter the biospecimen ordinal of the PRIMARY TUMOR TISSUE from which this model is derived.
Treatment Information				
79	History of neoadjuvant treatment	☐ No ☐ Yes; radiation prior to resection ☐ Yes; pharmaceutical treatment prior to resection ☐ Yes; both radiation and pharmaceutical treatment prior to resection ☐ Unknown	3382737	Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment. ***Note: Pharmaceutical therapy is addressed in Questions 80-86. Radiation therapy is addressed in Questions 87-88.***
80	Neoadjuvant chemotherapy type	☐ Cytotoxic chemotherapy ☐ Hormonal ☐ Immunotherapy (cellular and immune checkpoint) ☐ Targeted therapy (small molecule inhibitors and targeted antibodies) ☐ Not applicable	5832928	Select all neoadjuvant chemotherapy types that were administered to the patient. ***Note: Cytotoxic chemotherapy is addressed in Questions 81-82. Immunotherapy is addressed in Questions 83-84. Targeted therapy is addressed in Questions 85-86.***
81	Neoadjuvant chemotherapeutic regimen	☐ Carboplatin ☐ Cisplatin, 5-Fluorouracil (5-FU) and Trastuzumab ☐ Docetaxel ☐ Epirubicin ☐ Epirubicin, Cisplatin and 5-fluorouracil (ECF) ☐ Epirubicin, Cisplatin and Capecitabine (ECX) ☐ Epirubicin, Oxaliplatin, and Capecitabine (EOX) ☐ Irinotecan ☐ Oxaliplatin ☐ Paclitaxel ☐ Other (specify)	2853313	Select all chemotherapeutics used for neoadjuvant therapy. ***Note: If neoadjuvant chemotherapy was not given, skip to Question 83. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 81a, otherwise, skip to Question 82.***



Enrollment: Stomach

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
81a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapies administered.
82	Days to neoadjuvant chemotherapy treatment from index date	_____	5102411	Provide the number of days from index date to the date of treatment with neoadjuvant chemotherapy.
83	Immunotherapy	_____	2185614	Specify the name of the immunotherapy administered. ***Note: If immunotherapy was not given, skip to Question 85.***
84	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
85	Targeted Therapy	☐ Ramucirumab ☐ Trastuzumab ☐ Other (specify)	6005154	Select the targeted therapy administered to the patient. ***Note: If targeted therapy was not given, skip to Question 87. If the targeted therapy is not listed, proceed to Question 85a, otherwise, skip to Question 86.***
85a	Specify targeted therapy	_____	4308476	Provide the name of the targeted therapy administered to the patient.
86	Days to targeted therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with targeted therapy.
87	Radiation therapy administered type	☐ 2D conventional ☐ 3D conformal ☐ Brachytherapy HDR ☐ Brachytherapy LDR ☐ IMRT ☐ Proton Beam ☐ Stereotactic Body RT ☐ Stereotactic Radiosurgery ☐ WBRT ☐ Other (specify) ☐ Unspecified ☐ Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. ***Note: If radiation therapy was not administered, proceed to Question 89. If the radiation therapy is not listed, proceed to Question 87a, otherwise, skip to Question 88.***
87a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
88	Days to radiation treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with radiation therapy.
Metastatic/Recurrent Tumor Biospecimen Information				
89	Are you submitting a metastatic/recurrent tumor tissue sample?	☐ Yes ☐ No		Indicate whether a metastatic/ recurrent tumor biospecimen was collected for this ID3 case. ***Note: If yes, proceed to Question 90. If submitting an OTHER tissue sample, proceed to Question 155.***
90	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1", the second should be number "2", etc.***



Enrollment: Stomach

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
91	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
92	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
93	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
94	Number of days from index date to date of diagnosis of metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic/recurrent disease.
95	Method of metastatic/ recurrent cancer sample procurement	☐ Biopsy ☐ Fine needle aspiration ☐ Fluid drainage ☐ Surgical resection ☐ Other (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 95a, otherwise, skip to Question 96.***
95a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
96	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
97	Metastatic/recurrent site	☐ Antrum ☐ Body ☐ Fundus ☐ Gastroesophageal junction ☐ Pylorus ☐ Stomach (NOS) ☐ Ascites ☐ Liver ☐ Lung ☐ Lymph node ☐ Non-regional/distant lymph nodes ☐ Peritoneal surfaces ☐ Pleural effusion ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 97a, otherwise, skip to Question 98.***
97a	Other metastatic/ recurrent site	_____	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
98	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.



Enrollment: Stomach

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
99	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
100	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
101	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
102	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
103	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
104	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
105	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
Prognostic/Predictive/Lifestyle Features for Metastatic/Recurrent Tumor Prognosis or Responsiveness to Treatment				
106	Lymphovascular invasion present?	☐ Yes ☐ No ☐ Unknown	64727	Indicate whether large vessel (vascular) or small, thin-walled (lymphatic) invasion was detected in the tumor specimen.
107	Perineural invasion present?	☐ Yes ☐ No ☐ Unknown	64181	Indicate whether perineural invasion or infiltration is present.
108	Was HER2 IHC performed?	☐ Yes ☐ No ☐ Unknown	6063454	Indicate whether HER2 expression was assessed by immunohistochemistry (IHC). ***Note: If HER2 IHC was not performed, skip to Question 110.***
109	HER2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	2957563	Indicate the expression of HER2 as assessed by immunohistochemistry (IHC).
110	Was HER2 CISH/FISH performed?	☐ Yes ☐ No ☐ Unknown	6063447	Indicate whether HER2 was assessed by fluorescence in situ hybridization (FISH) or chromogenic in situ hybridization (CISH). ***Note: If HER2 FISH/CISH was not performed, skip to Question 116.***



Enrollment: Stomach

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
111	HER2 status by FISH/CISH	☐ Amplified ☐ Not amplified ☐ Equivocal	2854089	Select the HER2 status as assessed by FISH/CISH.
112	HER2 copy number	_____	3133738	If HER2 copy number testing was performed, provide the average number of HER2 fluorescence in situ hybridization (FISH) signals for the patient's metastatic/ recurrent tumor.
113	Centromere 17 copy number	_____	3104295	If Centromere 17 copy number testing was performed, provide the average number of Centromere 17 fluorescence in situ hybridization (FISH) signals for the patient's metastatic/ recurrent tumor.
114	Number of cells counted for HER2 and Centromere 17 copy numbers	_____	3087902	Provide the total number of cells counted to assess HER2 and Centromere 17 copy numbers.
115	HER2/Centromere 17 signal ratio	_____	2497552	If HER2 and Centromere 17 copy number analyses were performed by FISH, provide the ratio of the outcomes of these tests.
116	Tumor regression grade	☐ 0 (Complete response) ☐ 1 (Near complete response) ☐ 2 (Partial response) ☐ 3 (Poor or no response) ☐ Not assessed	6471217	Select the tumor regression grade that represents the histological response to neoadjuvant therapy.
Additional Metastatic/Recurrent Tumor Biospecimen Information (if applicable)				
117	Are you submitting an additional metastatic/ recurrent tumor tissue sample?	☐ Yes ☐ No		A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen. ***Note: If yes, proceed to Question 118, otherwise, skip to Question 145.***
118	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. The first biospecimen should be number "1," the second should be number "2," etc.
119	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.



Enrollment: Stomach

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
120	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
121	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/ recurrent tumor tissue sample collected for molecular characterization.
122	Number of days from index date to date of diagnosis of additional metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of additional metastatic/recurrent disease.
123	Method of metastatic/ recurrent cancer sample procurement	☐ Biopsy ☐ Fine needle aspiration ☐ Fluid drainage ☐ Surgical resection ☐ Other (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 123a, otherwise, skip to Question 124.***
123a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
124	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
125	Metastatic/recurrent site	☐ Antrum ☐ Body ☐ Fundus ☐ Gastroesophageal Junction ☐ Pylorus ☐ Stomach (NOS) ☐ Ascites ☐ Liver ☐ Lung ☐ Lymph node ☐ Non-regional/distant lymph nodes ☐ Peritoneal surfaces ☐ Pleural effusion ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 125a, otherwise, skip to Question 126.***
125a	Other metastatic/ recurrent site	_____	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
126	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
127	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
128	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.



Enrollment: Stomach

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
129	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
130	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
131	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
132	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
133	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
Prognostic/Predictive/Lifestyle Features for Additional Metastatic/Recurrent Tumor Prognosis or Responsiveness to Treatment				
134	Lymphovascular invasion present?	☐ Yes ☐ No ☐ Unknown	64727	Indicate whether large vessel (vascular) or small, thin-walled (lymphatic) invasion was detected in the tumor specimen.
135	Perineural invasion present?	☐ Yes ☐ No ☐ Unknown	64181	Indicate whether perineural invasion or infiltration is present.
136	Was HER2 IHC performed?	☐ Yes ☐ No ☐ Unknown	6063454	Indicate whether HER2 expression was assessed by immunohistochemistry (IHC). ***Note: If HER2 IHC was not performed, skip to Question 138.***
137	HER2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	2957563	Indicate the expression of HER2 as assessed by immunohistochemistry (IHC).
138	Was HER2 CISH/FISH performed?	☐ Yes ☐ No ☐ Unknown	6063447	Indicate whether HER2 was assessed by fluorescence in situ hybridization (FISH) or chromogenic in situ hybridization (CISH). ***Note: If HER2 FISH/CISH was not performed, skip to Question 144.***
139	HER2 status by FISH/CISH	☐ Amplified ☐ Not amplified ☐ Equivocal	2854089	Select the HER2 status as assessed by FISH/CISH.
140	HER2 copy number	_____	3133738	If HER2 copy number testing was performed, provide the average number of HER2 fluorescence in situ hybridization (FISH) signals for the patient's metastatic/recurrent tumor.



Enrollment: Stomach

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
141	Centromere 17 copy number	_____	3104295	If Centromere 17 copy number testing was performed, provide the average number of Centromere 17 fluorescence in situ hybridization (FISH) signals for the patient's metastatic/recurrent tumor.
142	Number of cells counted for HER2 and Centromere 17 copy numbers	_____	3087902	Provide the total number of cells counted to assess HER2 and Centromere 17 copy numbers.
143	HER2/Centromere 17 signal ratio	_____	2497552	If HER2 and Centromere 17 copy number analyses were performed by FISH, provide the ratio of the outcomes of these tests.
144	Tumor regression grade	☐ 0 (Complete response) ☐ 1 (Near complete response) ☐ 2 (Partial response) ☐ 3 (Poor or no response) ☐ Not assessed	6471217	Select the tumor regression grade that represents the histological response to neoadjuvant therapy.
Metastatic/Recurrent Tumor Model Information				
145	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
146	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
147	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
148	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
149	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Additional Metastatic/Recurrent Biospecimen Tumor Model Information (if applicable)				
150	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
151	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.



Enrollment: Stomach

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
152	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
153	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
154	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Other Biospecimen Information				
155	Are you submitting an OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an OTHER tissue sample (e.g. pre-malignant, non-malignant, or dysplastic tissue, etc.) was collected for HCMI for this case. ***Note: If yes, proceed to Question 156.***
156	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
157	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
158	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
159	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
160	Other method of cancer sample procurement	☐ Biopsy ☐ Fine needle aspiration ☐ Fluid drainage ☐ Surgical resection ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 160a, otherwise, skip to Question 161***
160a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
161	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
162	Tissue type	☐ Non-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 162a, otherwise, skip to Question 163.***



Enrollment: Stomach

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
162a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
163	Anatomic site of OTHER tissue	☐ Antrum ☐ Body ☐ Fundus ☐ Gastroesophageal Junction ☐ Pylorus ☐ Stomach (NOS) ☐ Ascites ☐ Liver ☐ Lung ☐ Lymph node ☐ Non-regional/distant lymph nodes ☐ Peritoneal surfaces ☐ Pleural effusion ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 163a, otherwise, skip to Question 164.***
163a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.
164	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
165	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Additional OTHER biospecimen Information (if applicable)				
166	Are you submitting an additional OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an additional OTHER tissue sample (pre-malignant, non-malignant, or dysplastic tissue, etc.) is being submitted for HCMI for this case. ***Note: If yes, proceed to Question 167. If no, proceed to Question 177.***
167	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. The first biospecimen should be number "1," the second should be number "2," etc.
168	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
169	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
170	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
171	Other method of cancer sample procurement	☐ Biopsy ☐ Fine needle aspiration ☐ Fluid drainage ☐ Surgical resection ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 171a, otherwise, skip to Question 172.***



Enrollment: Stomach

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

171a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
172	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
173	Tissue type	☐ Non-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 173a, otherwise, skip to Question 174.***
173a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
174	Anatomic site of OTHER tissue	☐ Antrum ☐ Body ☐ Fundus ☐ Gastroesophageal Junction ☐ Pylorus ☐ Stomach (NOS) ☐ Ascites ☐ Liver ☐ Lung ☐ Lymph node ☐ Non-regional/distant lymph nodes ☐ Peritoneal surfaces ☐ Pleural effusion ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 174a, otherwise, skip to Question 175.***
174a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.
175	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
176	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Other Tissue Model Information				
177	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
178	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
179	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
180	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
181	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.



Enrollment: Stomach

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Additional Other Tissue Model Information (if applicable)				
182	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
183	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
184	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
185	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
186	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.



Enrollment: Wilms Tumor

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Form Notes: An Enrollment Form should be completed for each HCMI case upon qualification notice from Leidos. All information provided on this form should include activity from the Date of Initial Pathologic Diagnosis to the most recent Date of Last Contact with the patient.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	☐ Initial pathologic diagnosis ☐ Sample procurement ☐ First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.
Normal Control Information				
4	Type of normal control	☐ Whole blood ☐ Buccal cells ☐ Buffy coat ☐ Lymphocytes ☐ Extracted DNA from blood ☐ Extracted DNA from saliva ☐ Extracted DNA from buccal cells ☐ Extracted DNA from normal tissue ☐ FFPE non-neoplastic tissue ☐ Non-neoplastic tissue	3081936	Indicate the type of normal control submitted for this case.
Tumor Tissue Collected for Molecular Characterization, Sample Information				
5	Tumor tissue sample preservation method	☐ FFPE ☐ Fresh ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the tumor tissue sample collected to be used for molecular characterization.
Cancer Model Information				
6	Anatomic site of tumor from which model was derived	☐ Abdomen ☐ Ascites ☐ Kidney ☐ Lung ☐ Lymph node ☐ Other (specify)	4214629	Indicate the anatomic site of the tumor tissue used to generate the model for the HCMI. ***Note: If the anatomic site of tumor tissue is not listed, proceed to Question 6a, otherwise, skip to Question 7.***
6a	Other anatomic site	_____	5946219	If the anatomic site for the tumor submitted to HCMI is not included on the provided list, specify the anatomic site.
7	Method of cancer sample procurement	☐ Core needle biopsy ☐ Excisional biopsy ☐ Fine needle aspiration ☐ Incisional biopsy ☐ Tumor resection ☐ Other (specify)	3103514	Indicate the procedure performed to obtain the tumor tissue used to generate the model for HCMI. ***Note: If the method of sample procurement is not listed, proceed to Question 7a, otherwise, skip to Question 8.***
7a	Other method of sample procurement	_____	2006730	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
8	Number of days from index date to date of cancer sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the tumor tissue submitted for HCMI.



Enrollment: Wilms Tumor

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
Completed By: _____ Completion Date (MM/DD/YYYY): _____

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
9	ICD-10 code for model tumor	☐ C64.1 ☐ C78.0 ☐ C64.2 ☐ C78.7 ☐ C64.9 ☐ C79.8 ☐ C77.9 ☐ Other (specify)	3226287	Provide the ICD-10 code for the tumor used to generate the model submitted to HCMI. ***Note: If the ICD-10 code is not listed, proceed to Question 9a, otherwise, skip to Question 10.***
9a	Other ICD-10 code	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.
10	Tumor tissue type	☐ Premalignant ☐ Primary ☐ Recurrent ☐ Metastatic ☐ Additional primary ☐ NOS	3288124	Provide the tumor tissue type for the biospecimen used to produce the model for the HCMI. ***Note: If 'Metastatic' is selected, continue to answer through Question 18. If the tissue is not 'Metastatic', skip to Question 19.***
Metastatic Model Information *(only complete Questions 11-18 if 'Metastatic' was selected in Question 10)*				
11	Age at diagnosis of metastasis	_____	6032752	Provide the age (in days) of the patient when diagnosed with metastatic disease. If the patient's age is greater than 32,507 days (89 years), please enter 32,507.
12	Number of days from index date to date of diagnosis of metastasis	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic disease.
13	Metastatic site	☐ Abdomen ☐ Liver ☐ Lung ☐ Lymph node(s); regional ☐ Lymph node(s); distant ☐ Other (specify)	6119068	Select the site from which the metastatic tissue used to develop the model was derived. ***Note: If the metastatic site is not listed, proceed to Question 13a, otherwise, skip to Question 14.***
13a	Other metastatic site	_____	3128033	If not included in the previous list, specify the site from which the metastatic tissue used to develop the model was derived.
14	Maintenance and/or consolidation therapy administered prior to collection of metastatic tissue	_____	6119066	If applicable, provide the name of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic tissue used to develop the model. ***Note: If maintenance and/or consolidation therapy was not administered, skip to Question 19.***
15	Days from index date to start of maintenance and/or consolidation therapy	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
16	Days from index date to last known date of maintenance and/or consolidation therapy treatment	_____	65167	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
17	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing treatment.



Enrollment: Wilms Tumor

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
18	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
Patient Information				
19	Gender	☐ Male ☐ Female ☐ Unspecified	2200604	Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
20	Height	_____	649	Provide the patient's height, in centimeters.
21	Weight	_____	651	Provide the patient's weight, in kilograms.
22	Body mass index (BMI)	_____	2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
23	Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown ☐ Not allowed to collect	2192199	Provide the patient's race using the defined categories. **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 peoples of the Far East, Southeast Asia, or in the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Phillippine Islands, Thailand, and Vietnam. **Black or African American:** A person having origins in any of the black racial groups of Africa. **Native Hawaiian or other Pacific Islander:** A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island. **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
24	Ethnicity	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Not allowed to collect	2192217	Provide the patient's ethnicity using the defined categories. **Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. **Not Hispanic or Latino:** A person not meeting the definition of Hispanic or Latino.
25	Year of birth	_____	2896954	Provide the year of the patient's birth. If the patient was born prior to 1928, insert the date 1928.
26	Family history of cancer	☐ Same ☐ Different ☐ None ☐ Unknown	5832923	Has a first-degree relative of the patient been diagnosed with a cancer of the same or a different type?
27	Smoking history	☐ Lifelong non-smoker (<100 cigarettes smoked in a lifetime) ☐ Current smoker (includes daily and non-daily smokers) ☐ Current reformed smoker (duration not specified) ☐ Current reformed smoker for >15 years ☐ Current reformed smoker for ≤15 years	2181650	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Primary Tumor Diagnosis Information				
28	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.
29	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. If the patient's age is greater than 32,507 days (89 years), please enter 32,507.
30	Morphology	☐ 8960/3 (Wilms tumor) ☐ Other (specify)	3226275	Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor. ***Note: If the morphology is not listed, proceed to Question 30a, otherwise, skip to Question 31.***
30a	Other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.
31	Tissue or organ of origin	☐ Kidney ☐ Other (specify)	3427536	Using the patient's pathology/laboratory report, select the primary site of the disease. ***Note: If the tissue or organ of origin is not listed, proceed to Question 31a, otherwise, skip to Question 32.***
31a	Other tissue or organ of origin	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	3427536	If the primary site of the disease is not included on the previous list, select the primary site of the disease.



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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
32	Histological type	_____	3294805	Provide the traditional surgical pathology text description of the histological tumor type.
33	Histology	☐ Favorable ☐ Unfavorable ☐ Unknown	4358735	Using the patient's pathology/laboratory report, select the histology of the tumor submitted to the HCMI.
34	Prior malignancy (of the same cancer type)	☐ Yes ☐ No ☐ Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
35	Prior malignancy (other cancer type)	☐ Yes ☐ No ☐ Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.
36	Tumor stage (pathological)	☐ Stage I ☐ γ-Stage I ☐ Stage II ☐ γ-Stage II ☐ Stage III ☐ γ-Stage III ☐ Stage IV	6013641	Using the patient's pathology/laboratory report, select the pathological stage as defined by SIOP/COG/NWTSG.
37	Metastasis at diagnosis assessment status	☐ Metastatic ☐ Non-metastatic (confirmed) ☐ Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor.
38	Metastatic site(s) at diagnosis	☐ Abdomen ☐ Liver ☐ Lung ☐ Lymph node(s); regional ☐ Lymph node(s); distant ☐ Other (specify)	3029815	Indicate all the site(s) of metastasis at the time of diagnosis of the primary tumor. ***Note: If the metastatic site(s) is not listed, proceed to Question 38a, otherwise, skip to Question 39.***
38a	Specify metastatic site(s)	_____	3128033	If the site(s) of metastasis at the time of diagnosis of the primary tumor is not included in the provided list, specify the site(s).
39	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, select all sites of relapse. ***Note: If the primary tumor did not relapse, select 'Not applicable'.***
40	Tumor weight (gross pathology)	_____	3184957	Provide the weight in grams of the primary tumor.
41	Tumor laterality	☐ Bilateral ☐ Left ☐ Right ☐ Unilateral; side not specified ☐ Midline ☐ Unknown	827	Indicate the side of the body on which the primary tumor was located.
Prognostic/Predictive/Lifestyle Features for Tumor Prognosis or Responsiveness to Treatment				
42	Anaplasia	☐ Absent ☐ Focal ☐ Diffuse ☐ Unknown	4925534	Indicate the presence of anaplasia in the primary tumor.
43	Wilms tumor related clinical syndrome name	☐ Beckwith-Wiedemann syndrome (BWS) ☐ Denys-Drash syndrome (DD) ☐ Hemihypertrophy (HH) ☐ WAGR syndrome (WAGR) ☐ Other ☐ None	3078770	Indicate whether the patient has any known clinical syndromes associated with Wilms tumor.



Enrollment: Wilms Tumor

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Treatment Information				
44	History of neoadjuvant treatment	☐ No ☐ Yes; radiation prior to resection ☐ Yes; pharmaceutical treatment prior to resection ☐ Yes; both radiation and pharmaceutical treatment prior to resection ☐ Unknown	3382737	Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment. ***Note: Radiation therapy is addressed in Questions 52-53. Pharmaceutical therapy is addressed in Questions 45-51.***
45	Neoadjuvant chemotherapy type	☐ Cytotoxic chemotherapy ☐ Hormonal ☐ Immunotherapy (cellular and immune checkpoint) ☐ Targeted therapy (small molecule inhibitors and targeted antibodies) ☐ Not applicable	5832928	Select all neoadjuvant chemotherapy types that were administered to the patient. ***Note: Cytotoxic chemotherapy is addressed in Questions 46-47. Immunotherapy is addressed in Questions 48-49. Targeted therapy is addressed in Questions 50-51.***
46	Neoadjuvant chemotherapeutic regimen	☐ Cyclophosphamide ☐ Dactinomycin ☐ Doxorubicin ☐ Etoposide ☐ Ifosfamide, Carboplatin, Cisplatin ☐ Irinotecan ☐ Vincristine ☐ Vincristine, actinomycin-D, cyclophosphamide (VAC) ☐ Vincristine, doxorubicin, cyclophosphamide, ifosfamide, etoposide (VDC/IE) ☐ Vincristine, actinomycin-D, cyclophosphamide, vincristine, irinotecan (VAC/VI) ☐ Ifosfamide, carboplatin, etoposide (ICE) ☐ Vincristine, irinotecan, temozolomide (VIT) ☐ High-dose methotrexate, doxorubicin, cisplatin (MAP) ☐ Other (specify) ☐ Chemotherapy not given	2853313	Select all chemotherapeutics used for neoadjuvant therapy. ***Note: If neoadjuvant chemotherapy was not given, skip to Question 48. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 46a, otherwise, skip to Question 47.***
46a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapy.
47	Days to neoadjuvant chemotherapy treatment from index date	_____	5102411	Provide the number of days from index date to the date of treatment with neoadjuvant chemotherapy.
48	Immunotherapy name, specify	_____	2185614	Specify the name of the immunotherapy administered. ***Note: If immunotherapy was not given, skip to Question 50.***
49	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.



Enrollment: Wilms Tumor

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
50	Targeted molecular therapy name, specify	_____	2842797	Specify the targeted therapy administered to the patient. ***Note: If targeted therapy was not given, skip to Question 52.***
51	Days to targeted therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with targeted therapy.
52	Radiation therapy administered type	☐ 2D conventional ☐ 3D conformal ☐ Brachytherapy HDR ☐ Brachytherapy LDR ☐ IMRT ☐ Proton Beam ☐ Stereotactic Body RT ☐ Stereotactic Radiosurgery ☐ WBRT ☐ Other (specify) ☐ Unspecified ☐ Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. ***Note: If radiation therapy was not administered, skip the remaining questions. If the radiation therapy is not listed, proceed to Question 52a, otherwise, skip to Question 53.***
52a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
53	Days to radiation treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with radiation therapy.