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, Epithelial 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.

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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".***

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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.

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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.

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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.

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
34	Histological Type	☐ Bladder cancer ☐ Bone Cancer ☐ Chordoma ☐ Duodenal gastrinoma ☐ Epithelial 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).

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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.

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

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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.

Enrollment: Rare

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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.***

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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
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.

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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
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

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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.

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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): _____
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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): _____
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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): _____

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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): _____
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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): _____
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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).