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Enrollment: Rare	
HCMI Identifier (ID3):	
Completion Date (MM/DD/YYYY):	
	HCMI Identifier (ID3):

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 $Cholangio carcinoma, Gall bladder \ Cancer, \ Malignant \ Spindle \ Cell \ Neoplasm, \ Mullerian \ Carcinoma, Small \ Intestine \ Cancer, \ and \ Thyroid \ Cancer.$

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 Info			1	T
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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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		6379572	Provide the age (in days) of the patient on the
	index date			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	☐ Same	5832923	Has a first-degree relative of the patient been
13	cancer	☐ Different	3032323	diagnosed with a cancer of the same or a
		□ None		different type?
14	Smoking history	☐ Unknown ☐ Lifelong non-smoker (<100 cigarettes	2181650	Indicate the patient's history of tobacco
14	Silloking instory	smoked in a lifetime)	2101030	smoking as well as their current smoking status
		☐ Current smoker (includes daily and non-		using the defined categories.
		daily smokers)		
		☐ Current reformed smoker (duration not specified)		
		☐ Current reformed smoker for >15 years		
		☐ Current reformed smoker for ≤15 years		
15	Daily alcohol consumption		3124961	Indicate the patient's daily alcohol consumption as self-reported by the patient.
	(drinks per day)			consumption as sentieported by the patient.
15a	Frequency of		3114013	Provide the average number of days each week
	alcohol			that the patient consumes an alcoholic
	consumption days per week			beverage.
16	Infection history?	☐ Yes	2816879	Indicate whether the patient has a history of
		□ No		relevant infectious disease.
16a	Specify relevant	☐ Unknown	3233643	Specify the name of the relevant infectious
100	infectious disease		3233043	disease.
17	Asbestos	☐ Yes	1253	Indicate whether the patient has been exposed
	exposure?	□ No		to asbestos.
18	Metastasis at	☐ Unknown ☐ Metastatic	3438571	Indicate whether there was evidence of
	diagnosis	☐ Non-metastatic (confirmed)		metastasis at the time of diagnosis of the
	assessment status	☐ Non-metastatic (unconfirmed)		primary tumor. Note: If metastatic at diagnosis, proceed to Question 18a, otherwise, skip to
				Question 19.
18a	Metastatic site(s)	☐ Ascites ☐ Lung	3029815	Indicate the site(s) of metastasis at the time of
	at diagnosis	☐ Bone ☐ Lymph node(s)		diagnosis of the primary tumor. Note: If the anatomic site of tumor tissue is not
		☐ Brain ☐ Skin ☐ Spinal cord		listed, proceed to Question 18a, otherwise, skip to
		☐ Liver ☐ Other (specify)		Question 19.
18b	Specify metastatic		3128033	If the site of metastasis is not included on the
	site(s)			provided list, specify the site of metastasis.
Biospecime	n Information			
19	Tissue sample	☐ Normal tissue	2006911	Please select all the tissue sample types
	type(s) collected for HCMI for this	☐ Primary tumor ☐ Metastatic		submitted for HCMI with this case.
	case	Recurrent		
		☐ Othertissue		
20	Number of		6584256	Please provide the number of normal tissue
	NORMAL tissue biospecimens			specimens obtained for HCMI for this case. Note: This number is expected to be "1".
	collected for			
	HCMI for this			
	case		<u> </u>	

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Enrollment: Rare	VAL.
HCMI Identifier (ID3):	1
Completion Date (MM/DD/YYYY):	100



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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 tum 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 primar 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 sit at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. 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-malignal non-malignant, or dysplastic tissue biospecimens collected for HCMI for this case. Note: A biospecimen obtained from a single sit at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. 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 Co	ntrol 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

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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
28 28	Type of normal control Other anatomic	 □ 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. If non-neoplastic tissue, adjacent tissue, or
20d	site of normal tissue		3200109	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.
31	nor Biospecimen Info	C17.0	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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Tissue Source Site (TSS) Name:Completed By:	Enrollment: Rare HCMI Identifier (ID3): Completion Date (MM/DD/YYYY):	

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
32	Tumor Morphology	□ 8013/3 □ 8240/3 □ 8510/3 □ 8020/3 □ 8243/3 □ 8560/3 □ 8031/3 □ 8244/3 □ 8588/3 □ 8032/3 □ 8246/3 □ 8589/3 □ 8041/3 □ 8249/3 □ 8801/3 □ 8051/3 □ 8310/3 □ 8804/3 □ 8070/3 □ 8330/3 □ 8950/3 □ 8074/3 □ 8430/3 □ 9370/3 □ 8083/2 □ 8345/3 □ 9371/3 □ 8120/3 □ 8346/3 □ 9372/3 □ 8131/3 □ 8480/3 □ Other □ 8144/3 □ 8153/3	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 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 □ Ovary □ Bone □ Small intestine □ Connective □ Skin tissue □ Thyroid gland □ Extrahepatic bile □ Uterus duct □ Other site □ Gallbladder (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 □ Peritoneum □ Accessory sinus □ Pharynx □ Adrenal gland □ Pituitary gland □ Anus □ Prostate gland □ Appendix □ Rectosigmoid junction □ Connective, subcutaneous and other soft tissues □ Retroperitoneum □ Appendix □ Renal pelvis □ Retroperitoneum Spinal cord □ Spleen □ Spleen □ Esophagus □ Stomach □ Eye □ Testis □ Gum □ Thymus □ Head, face or neck □ Tongue □ Heart Other illdefined sites □ Unknown □ Palate □ Urinary system □ Penis □ Vagina □ Peripheral nerves and autonomic nervous system of trunk	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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	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	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 ☐ 5th ☐ 2nd ☐ 6th ☐ 3rd ☐ 7th ☐ 4th ☐ 8th	2722309	Select the AJCC staging handbook edition used to stage the patient's primary tumor.
38	AJCC clinical stage group	□ Stage 0 □ Stage IIC □ Stage 0is □ Stage III □ Stage I □ Stage IIIA □ Stage IA □ Stage IIIB □ Stage IA1 □ Stage IIIC □ Stage IA2 □ Stage IV □ Stage IA3 □ Stage IVA □ Stage IB □ Stage IVB □ Stage IB1 □ Stage IVC □ Stage IB2 □ Stage IS □ Stage II □ Stage Tis □ Stage IIA □ Stage X □ Stage IIB □ 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 □ T2a2 □ T4c □ T1 □ T2b □ T4d □ T1a □ T2c □ T4e □ T1a1 □ T2d □ T5 □ T1a2 □ T3 □ Tis □ T1b □ T3a □ Tis (AIS) □ T1b1 □ T3b □ Tis (DCIS) □ T1b2 □ T3c □ Tis (LCIS) □ T1c □ T3d □ Tis □ T1mi □ T4 (Paget's) □ T2 □ T4a □ Tis (SCIS) □ T2a □ T4b □ TX □ T2a1 □ 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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V3.0	Enrollment: Rare	
Tissue Source Site (TSS) Name:	HCMI Identifier (ID3):	1 38
Completed By:	Completion Date (MM/DD/YYYY):	

Question	Question Text	Data Entry Opt	ions	CDE ID	Instruction Text
40	AJCC pathologic spread: Lymph nodes (pN)	□ N0 □ N0 (i+) □ N0 (i-)	□ N1mi □ N2 □ 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
	,	□ N0 (mol+) □ N0 (mol-)	□ N2b □ N2c		Cancer (AJCC).
		□ N1 □ N1a □ N1b	□ N3 □ N3a □ N3b		
		□ N1bl □ N1bll	□ N3c □ N4		
		□ N1bIII □ N1bIV	□ NX□ Not applicable		
4.1	ALCC mathalasia	□ N1c	□ M1 a	2045420	
41	AJCC pathologic spread: Distant metastases (pM)	□ M0 □ M1 □ M1a	☐ M1c ☐ M2 ☐ 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
		☐ M1b	☐ Not applicable		Cancer (AJCC).
42	AJCC tumor stage (pathological)	□ 0 □ 0a	□ IIA2 □ IIB	3065862	Using the patient's pathology/laboratory report, in conjunction with the patient's medical record,
		□ 0is □ I □ IA	□ IIC □ III □ IIIA		select the stage as defined by the American Joint Committee on Cancer (AJCC).
		□ IA1 □ IA2			
		□ IB □ IB1	□ IV □ IVA		
		□ IB2 □ IC	□ IVB □ IVC		
		□ II □ IIA □ IIA1	☐ Tis ☐ X ☐ Not applicable		
43	Tumor grade	☐ G1-Well differe	entiated	2785839	Using the patient's pathology/laboratory report, select the grade of the primary tumor, if
		☐ G3-Poorly diffe☐ G4-Undifferent☐	iated		applicable.
		☐ GB-Borderline I☐ GX-Unknown☐ Not applicable	histologic grade		
44	Lymphatic invasion present?	☐ Yes ☐ No		64171	Indicate if malignant cells are present in small or thin-walled vessels, suggesting lymphatic
45	Is necrosis present?	☐ Unknown ☐ Yes ☐ No		64740	involvement. Indicate whether there is evidence of localized death of living cells within the tumor.
		☐ Unknown			
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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Tissue Source Site (TSS) Name: ______Completed By: _____ HCMI Idei Completion Date (MM/DD/YYYY):

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Primary Tun	nor Sample Informati	on		
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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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	MMR status	☐ Evidence of MN	AR mutation by	6002208	Indicate the patient's Mismatch Repair (MMR)
00	William Status	sequencing	in matation by	0002200	gene mutation status.
		, ,	MR protein loss by IHC		gene mutation status.
			ence hypermutation		
			Omutations/Mb)		
		☐ No evidence of	MMR alteration		
61	MYCN gene	☐ Amplified		4616052	Indicate the amplification status of the MYCN
	amplification	☐ Not amplified			gene.
	status	□ Not done			
		☐ Unknown			
62	MLH1 promoter	☐ MLH1 promote	r hypermethylation	6033150	Indicate the methylation status of the MLH1
	methylation	present			promoter.
	status	☐ MLH1 promote	r hypermethylation		
		absent	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
			r hypermethylation not		
		assessed	i nypermetnyiation not		
		□ Indeterminate			
63	Was HER2	indeterminate		6063447	Indicate whether HER2 was assessed by
03		☐ Yes		0003447	•
	FISH/CISH	□ No			fluorescence in situ hybridization (FISH) or
	performed?	☐ Unknown			chromogenic in situ hybridization (CISH).
					Note: If yes, proceed to Questions 63a-e.
63a	HER2 status by	☐ Amplified		2854089	Select the HER2 status as assessed by FISH/CISH
	FISH/CISH	☐ Not amplified			
		☐ Equivocal			
63b	HER2 copy			3133738	If HER2 copy number testing was performed,
	number				provide the average number of HER2
					fluorescence in situ hybridization (FISH) signals
			_		for the patient's primary tumor.
63c	Centromere 17			3104295	If Centromere 17 copy number testing was
	copy number			010.1200	performed, provide the average number of
	,				Centromere 17 fluorescence in situ hybridizatio
			_		(FISH) signals for the patient's primary tumor.
63d	Number of cells			3087902	Provide the total number of cells counted to
osu	counted for HER2			3087902	
					assess HER2 and Centromere 17 copy numbers.
	and Centromere		_		
	17 copy numbers				
63e	HER2/Centromere			2497552	If HER2 and Centromere 17 copy number
	17 signal ratio				analyses were performed by FISH, provide the
			_		ratio of the outcomes of these tests.
rimary Tu	nor Mutational Analy	rses			
64	Was mutation				Select the gene(s) for which mutation analysis
	analysis				was performed.
	performed for any				Note: If ALK is selected, proceed to Question 65; if
	of the following	☐ ALK	□ IDH1/2		BRAF is selected, proceed to Question 66; If CDKN2A
	genes?	□ BRAF	☐ KRAS		selected, proceed to Question 67; If EGFR is selected
	30	☐ CDKN2A	☐ PIK3CA		proceed to Question 68; If GNAS is selected, proceed
		☐ EGFR	☐ PTEN		to Question 69; If H3 K27 is selected, proceed to
		☐ GNAS	☐ TP53		Question 70; If IDH1/2 is selected, proceed to
		□ H3 K27	<u> пгээ</u>		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
65	Was a mutation in	☐ Yes		3774202	selected, proceed to Question 75. Indicate whether a mutation in ALK was
55	ALK identified?	□ No		3,77202	identified. Note: If yes, proceed to Question 65a.
65.	If ALK mutation	□ F1174L	□ E1174C	6060270	Select the ALK mutation identified.
65a			☐ F1174C	6060279	Note: If the ALK mutation is not listed, proceed to
	identified, which	☐ K1062M	☐ F1174V		Question 65b.
	one?	☐ R1275Q	☐ F1245L	1	22230000
		□ T1087I	Other (specify)		

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V3.0		HCMI
	Enrollment: Rare	
Tissue Source Site (TSS) Name:	HCMI Identifier (ID3):	
Completed By:	Completion Date (MM/DD/YYYY):	100000000000000000000000000000000000000

Question	Question Text	Data Entry Options		CDE ID	Instruction Text
65b	Other ALK			6101680	If the ALK mutation identified is not included in
	mutation				the provided list, specify the ALK mutation
					identified.
66	Was a mutation in	☐ Yes		6061809	Indicate whether a mutation in BRAF was
	BRAF identified?	□ No			identified through mutation analysis.
					Note: If yes, proceed to Question 66a.
66a	If BRAF mutation	□ V600E		6061810	Indicate the specific BRAF mutation identified.
	identified, which	□ V600D			Note: If the BRAF mutation is not listed, proceed to
	one?	□ V600K			Question 66b.
		□ V600R			
		☐ K601E			
		☐ Other (specify)			
66b	Other BRAF			6101687	If the BRAF mutation is not included in the list
	mutation				provided, specify the BRAF mutation identified.
66c	What sequencing	☐ Next generation targ		6003729	Select the sequencing assay used to identify the
	assay was used to	☐ Whole exome seque	encing		somatic mutation.
	identify the BRAF	☐ Other (specify)			Note: If the sequencing assay is not listed, proceed to
	mutation?				Questions 66d.
66d	Other sequencing			6002204	If the sequencing assay is not included in the
	assay				provided list, specify the other sequencing assay.
67	Was a mutation in	□ Yes		6063534	Indicate whether a mutation in CDKN2A was
	CDKN2A	□ No			identified through mutation analysis.
	identified?				Note: If yes, proceed to question 67a.
67a	If CDKN2A	□ A30V	□ D108Y	6063732	Indicate the specific CDKN2A mutation identified
	mutation	II V51D	☐ L130Q		Note: If the CDKN2A mutation is not listed, proceed to
	identified, which	⊔ V51I	☐ A147T		Question 67b.
	one?	⊔ Н83Р	□ A148T		
		☐ H83Y	☐ Other (specify		
		□ D108H	- other (speem)		
67b	Other CDKN2A			6101684	If the CDKN2A mutation identified is not provided
	mutation(s)				in the previous list, specify the CDKN2A mutation.
68	Was a mutation in	□ Yes		6063530	Indicate whether a mutation in EGFR was
	EGFR identified?	□ No			identified through mutation analysis.
CO-		П 6740V	П г 10	2447627	Note: If yes, proceed to Question 68a.
68a	If CCCD moutation	☐ G719X ☐ T790M	Exon 19	3147627	Indicate the specific EGFR mutation identified. Note: If the EGFR mutation is not listed, proceed to
	If EGFR mutation		deletion		Question 68b.
	identified, which		Exon 20		Question obs.
	one?	☐ L858R	insertion		
COh	Other EGFR	☐ L861Q	☐ Other (specify	4172002	If the ECED mutation identified is not provided in
68b	mutation(s)			4173882	If the EGFR mutation identified is not provided in
69	Was a mutation in	□ Yes		5983161	the previous list, specify the EGFR mutation. Indicate whether a mutation in GNAS was
09	GNAS identified?	□ No		3903101	identified through mutation analysis.
	GNAS Identified:	LI NO			Note: If yes, proceed to Question 69a.
69a	If GNAS mutation	□ Q125R	□ Q227E	6063733	Indicate the specific GNAS mutation identified.
	identified, which		☐ Q227L		Note: If the GNAS mutation is not listed, proceed to
	one?		☐ Q227P		Question 69b.
	one.		☐ Q227R		
			☐ Other (specify		
69b	Other GNAS		V1 1	6101685	If the GNAS mutation identified is not provided in
	mutation(s)			<u> </u>	the previous list, specify the GNAS mutation.
70	Was a mutation in	☐ Yes		6002202	Indicate whether H3 K27 mutation was identified.
	H3 K27 identified?	□ No		<u> </u>	Note: If yes, proceed to Question 70a.
70a	If H3 K27			6002205	Select the H3 K27 mutation identified.
	mutation	□ H3.1			
	identified, in	☐ H3.3			
	which variant was	☐ Other			
	it found?			1	

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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
71	Was a mutation in	, ,	6002200	Indicate whether an IDH1 or IDH2 mutation was
	IDH1/2 identified?	☐ Yes		identified at testing.
	·	□ No		Note: If yes, proceed to Question 71a.
71a	If IDH1/2	☐ IDH1 R132H ☐ IDH2 R173W	6002206	Select the mutation identified in IDH1/2.
	mutation	☐ IDH2 R172W		Note: If the IDH1/2 mutation is not listed, proceed to
	identified, which	☐ IDH1 R132S ☐ IDH2 R172K ☐ IDH2 R172M		Question 71b.
	one?	I □ IDH1 R132G		
		☐ IDH1 R132L ☐ Other (specify)		
71b	Other IDH1/2		6002207	If the mutation in IDH1/2 is not included in the
	mutation			provided list, specify the mutation in IDH1/2.
71c	What sequencing	☐ Next generation targeted sequencing	6003729	Select the sequencing assay used to identify the
	assay was used to	☐ Whole exome sequencing		somatic mutation.
	identify the	☐ Not performed		Note: If the sequencing assay is not listed, proceed to
	IDH1/2 mutation?	☐ Other (specify)		Question 71d.
71d	Other sequencing		6002204	If the sequencing assay is not included in the
	assay			provided list, specify the other sequencing assay.
72	Was a mutation in	☐ Yes	6060081	Indicate whether a mutation in KRAS was
	KRAS identified?	□ No		identified through mutation analysis.
72a	If KRAS mutation	G13V	6060083	Note: If yes, proceed to Question 72a.
/ Z a	identified, which	□ G12A □ G12V □ Q61H	8800000	Indicate the specific KRAS mutation identified. Note: If the KRAS mutation is not listed, proceed to
	one?	☐ G12C ☐ G13A ☐ Q61L		Question 72b.
	one:	☐ G12D ☐ G13C ☐ G146T		3
		☐ G12R ☐ G13D ☐ Other		
		☐ G12S ☐ G13R ☐ Gther (specify)		
72b	Other KRAS	(зреспу)	6101691	If the KRAS mutation identified is not provided in
725	mutation		0101031	the previous list, specify the KRAS mutation.
73	Was a mutation in		6063524	Indicate whether a mutation in PIK3CA was
	PIK3CA identified?	Yes		identified through mutation analysis.
		□ No		Note: If yes, proceed to Question 73a.
73a	If PIK3CA		6063735	Indicate the specific exon of the PIK3CA gene in
	mutation			which the mutation was identified.
	identified, in what	□ 20 □ 20 □ 20 □ 20 □ 20 □ 20 □ 20 □ 20		Note: If the PIK3CA mutation is not listed, proceed to
	exon?	☐ Other (specify)		Question 73b.
73b	Other PIK3CA		6101688	If the specific exon of the PIK3CA gene mutation
	mutation			abnormality identified was not included in the
				previous list, please specify the exon.
74	Was a mutation in	☐ Yes	6063529	Indicate whether a mutation in PTEN was
	PTEN identified?	□ No		identified through mutation analysis.
74:	If DTEN	-	6062726	Note: If yes, proceed to Question 74a.
74a	If PTEN mutation	☐ Exon 1-9 mutation present	6063736	Indicate whether a mutation in exon 1-9 of PTEN
1	identified, which	☐ Cannot be determined		was identified. Note: If the PIK3CA mutation is not listed, proceed to
1	one?	☐ Other (specify		Question 74b.
74b	Other PTEN		6101689	If the PTEN gene mutation identified is not in
	mutation			exons 1-9, please specify the exon.
75	Was a mutation in		6063523	Indicate whether a mutation in TP53 was
	TP53 identified?	☐ Yes		identified through mutation analysis.
		□ No		Note: If yes, proceed to Question 75a.
75a	If TP53 mutation	□ R175H □ G266V	6063731	Indicate the specific TP53 mutation identified.
1	identified, which	□ R213L □ V272M		Note: If the TP53 mutation is not listed, proceed to
1	one?	□ Y220C □ R273C		Question 75b.
		□ C238Y □ R273H		
		□ G245D □ R273I		
		□ G2455 □ P282G		
1		□ R248Q □ R282W		
		☐ R248W ☐ Other (specify		
		☐ G266E		

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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
75b	Other TP53	, ,	610168	If the TP53 mutation identified is not provided in
	mutation(s)			the previous list, specify the TP53 mutation.
75c	What sequencing	☐ Next generation targeted	sequencing 600372	Select the sequencing assay used to identify the
	assay was used to	☐ Whole exome sequencing	g	somatic mutation.
	identify the TP53	☐ Not performed		Note: If the sequencing assay is not listed, proceed to
	mutation?	☐ Other (specify)		Question 75d.
75d	Other sequencing		600220	If the sequencing assay is not included in the
	assay			provided list, specify the other sequencing assay.
	nor Protein Expression	n Information		-
76	Was IHC			Select the protein(s) for which IHC was
	performed in any			performed.
	of the following	П . ВВАЕ V6005		Note: If BRAF V600E is selected, proceed to Question
	proteins?	□ BRAF V600E □ N	1SH6	77; If ER is selected, proceed to Question 78. If H3 K27M is selected, proceed to Question 79; If HER2 is
			MS2	selected, proceed to Question 80; If IDH1 R132H is
		☐ H3 K27M ☐ P	D-L1	selected, proceed to Question 81; If MLH1 is selected,
		HER2 P	R	proceed to Question 82; If MSH2 is selected, proceed to
		☐ IDH1 R132H ☐ P ☐ MLH1 ☐ P	TEN	Question 83; If MSH6 is selected, proceed to Question
		☐ MSH2 ☐ SI	MAD4	84; If PMS2 is selected, proceed to Question 85; If PD-
		□ IVISH2		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	☐ Positive	642812	
	expression by IHC	☐ Negative		immunohistochemistry (IHC).
		☐ Equivocal		Ι Ι Ι Ι Ι Ι Ι Ι Ι Ι Ι Ι Ι Ι Ι Ι Ι Ι Ι
78	Estrogen Receptor		241921	Indicate the numeric Allred score (cell staining
	(ER) Allred score			percentage plus intensity) for estrogen receptor.
		□ 3 □ 7		
		□ 4		
79	H3 K27M	☐ Positive	600220	Indicate the expression of H3 K27M by
	expression by IHC	□ Negative		immunohistochemistry (IHC).
		☐ Equivocal		
80	HER2 expression	☐ Positive	295756	Indicate the expression of HER2 as assessed by
	by IHC	☐ Negative		immunohistochemistry (IHC).
		☐ Equivocal		
81	IDH1 R132H	☐ Positive	606367	' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' '
	expression by IHC	□ Negative		assessed by immunohistochemistry (IHC).
		☐ Equivocal		
82	MLH1 expression	☐ Positive	606366	Indicate the status of MLH1 protein expression as
	by IHC	□ Negative		determined by immunohistochemistry (IHC).
		☐ Equivocal		
83	MSH2 expression	☐ Positive	6063669	Indicate the status of MSH2 protein expression as
	by IHC	☐ Negative		determined by immunohistochemistry (IHC).
		☐ Equivocal		
84	MSH6 expression	☐ Positive	606367	Indicate the status of MSH6 protein expression as
	by IHC	☐ Negative		determined by immunohistochemistry (IHC).
		☐ Equivocal		
85	PMS2 expression	☐ Positive	606367	Indicate the status of PMS2 protein expression as
	by IHC	☐ Negative		determined by immunohistochemistry (IHC).
	'	☐ Equivocal		, , , , , , , , , , , , , , , , , , , ,
86	PD-L1 expression	☐ Positive	479863	Indicate the status of PD-L1 protein expression as
	by IHC	☐ Negative	473003	determined by immunohistochemistry (IHC).
	,	_		determined by minimum strothermistry (mrc).
87	Progestorons	☐ Equivocal	606367	3 Indicate the expression of progesterone receptor
0/	Progesterone	☐ Positive	000367.	as assessed by immunohistochemistry (IHC).
	receptor (PR)	□ Negative		as assessed by initialionistochemistry (inc).
	expression by IHC	☐ Equivocal		

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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
88	PTEN expression	☐ Positive	6063672	Indicate the status of PTEN protein expression as
	by IHC	☐ Negative		determined by immunohistochemistry (IHC).
		☐ Equivocal		
89	SMAD4	☐ Positive	6063676	Indicate the status of SMAD4 protein expression
	expression by IHC	☐ Negative		as determined by immunohistochemistry (IHC).
		☐ Equivocal		
Primary Tur	nor Model Informatio		I.	
90	Primary model		6594596	Please provide a number to identify
	biospecimen			which biospecimen this is in the sequence.
	ordinal .			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		6584919	Please provide the BPC-generated ID for this
	(if available)			sample as it will appear on the Sample
				Submission Form transmitted to the BPC.
93	Model represents		6584730	Does this MODEL represent the PRIMARY
	primary	☐ Yes		DIAGNOSIS for this case ID3?
	diagnosis?	□ No		
94	Model's primary		6586035	Enter the CMDC Sample ID of the PRIMARY
	tumor tissue			TUMOR TISSUE from which this model is derived
	CMDC sample ID			
95	Model's primary		6584265	Enter the biospecimen ordinal of the PRIMARY
	tumor			TUMOR TISSUE from which this model is derived
	biospecimen			
	ordinal			
Treatment i	Information			
96	History of	□ No	3382737	Indicate whether the patient received
	neoadjuvant	Yes; radiation prior to resection		neoadjuvant radiation or pharmaceutical
	treatment	Yes; pharmaceutical treatment prior to		treatment.
		resection		Note: Radiation therapy is addressed in Questions 10
		Yes; both radiation and pharmaceutical		107. Pharmaceutical therapy is addressed in Question
		treatment prior to resection		97-105.
		☐ Unknown		
97	Neoadjuvant	Cytotoxic chemotherapy	5832928	Select all neoadjuvant chemotherapy types that
	chemotherapy	☐ Hormonal		were administered to the patient.
	type	☐ Immunotherapy (cellular and immune		Note: Cytotoxic chemotherapy is addressed in
		checkpoint)		Questions 98-99. Hormonal therapy is addressed in
		☐ Targeted therapy (small molecule		Questions 100-101. Immunotherapy is addressed in Questions 102-103. Targeted therapy is addressed in
		inhibitors and targeted antibodies)		Questions 104-105.
		□ Not applicable		,
98	Neoadjuvant	☐ 5-fluorouracil ☐ Lapatinib		Select all chemotherapeutics used for
	chemotherapeutic	☐ Albumin-bound ☐ Liposomal		neoadjuvant therapy.
	regimen	paclitaxel Doxorubicin		Note: If neoadjuvant chemotherapy was not given,
		☐ Capecitabine ☐ Methotrexate		skip to Question 100. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to
		☐ Carboplatin ☐ Mitoxantrone		Question 98a, otherwise, skip to Question 99.
		☐ Cisplatin ☐ Neratinib		The state of the s
		☐ Cyclophos- ☐ Paclitaxel		
		phamide	2853313	
		☐ Docetaxel ☐ Trastuzumab		
		☐ Epirubicin ☐ VinoreIbine		
		☐ Eribulin ☐ Other (specify)		
		☐ Gemcitabine ☐ Chemotherapy		
		☐ Ixabepilone not given		

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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
98a	Other		62694	If the neoadjuvant therapy is not included in the
	neoadjuvant			provided list, specify neoadjuvant therapies
	chemotherapeutic			administered.
	regimen			
99	Days to		5102411	Provide the number of days from index date to
	neoadjuvant			the date of treatment with neoadjuvant
	chemotherapy			chemotherapy.
	treatment from			
	index date			
100	Specify hormone		2405358	Provide the name of the hormone therapy
	therapy			administered to the patient.
101	Days to hormone		5102411	Provide the number of days from the index date
	therapy treatment			to the date of treatment with hormone therapy
	from index date			
102	Specify		2953828	Provide the name of the immunotherapy
102	immunotherapy		2333020	administered to the patient.
103	Days to		5102411	Provide the number of days from the index date
103	immunotherapy		3102411	to the date of treatment with immunotherapy.
	treatment from			to the date of treatment with minunotherapy.
	index date			
104			4200476	Dravida the name of the targets of the renu
104	Specify targeted		4308476	Provide the name of the targeted therapy
405	therapy		5400444	administered to the patient.
105	Days to targeted		5102411	Provide the number of days from the index date
	therapy treatment			to the date of treatment with targeted therapy.
	from index date			
106	Radiation therapy	☐ 2D conventional	3028890	Provide the type of radiation therapy that was
	administered type	☐ 3D conformal		administered to the patient.
		☐ Brachytherapy HDR		Note: If radiation therapy was not administered, skip
		☐ Brachytherapy LDR		the remaining questions. If the radiation therapy is
		☐ IMRT		not listed, proceed to Question 106a, otherwise, skip to Question 107.
		☐ Proton Beam		to Question 107.
		☐ Stereotactic Body RT		
		☐ Stereotactic Radiosurgery		
		☐ WBRT		
		☐ Other (specify)		
		☐ Unspecified		
		☐ Not applicable		
106a	Other radiation		2195477	If the radiation therapy type is not included in
	therapy			the provided list, specify the type.
107	Days to radiation		5102411	Provide the number of days from the index date
10,	treatment from		3102411	to the date of treatment with radiation therapy.
	index date			to the date of treatment with radiation therapy.
Metastatic		ı specimen Information		
108				Indicate whether a metactatic/recurrent times
TOQ	Are you			Indicate whether a metastatic/recurrent tumor
	submitting a	☐ Yes		biospecimen was collected for this ID3 case.
	metastatic/	□ No		Note: If yes, proceed to Question 109. If submitting an OTHER tissue sample, proceed to Question 152.
	recurrent tumor			un OTHER tissue sumple, proceed to Question 132.
	tissue sample?			
109	Metastatic tissue		6584266	Please provide a number to identify which
	biospecimen			biospecimen this is in the sequence.
	ordinal			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
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				Sample Submission Form transmitted to the

V3.0		HCMI	-9
	Enrollment: Rare		
Tissue Source Site (TSS) Name:	HCMI Identifier (ID3):	44	
Completed By:	Completion Date (MM/DD/YYYY):		

Question	Question Text	Data Entry Options		CDE ID	Instruction Text
111	BPC submitter ID	, , , , , , , , , , , , , , , , , , , ,		6584919	Please provide the BPC-generated ID for this
	(if available)				sample as it will appear on the Sample
					Submission Form transmitted to the BPC.
112	Metastatic/			5432521	Provide the method used to preserve the
	recurrent tumor	☐ Cryopreserved	☐ Frozen		metastatic/recurrent tumor tissue sample
	tissue sample	☐ FFPE	□ ост		collected for molecular characterization.
	preservation	☐ Fresh	☐ Snap frozen		
	method		•		
113	Number of days			6132218	Provide the number of days from the index date
	from index date to				to the date of diagnosis of metastatic/recurrent
	date of diagnosis				disease.
	of metastasis/				
	recurrence				
114	Method of	☐ Tumor resection		6587389	Indicate the procedure performed to obtain the
	metastatic/	□ Biopsy			metastatic/recurrent tumor tissue.
	recurrent cancer	☐ Core needle biops	ïy		Note: If the method of procurement is not listed,
	sample	☐ Incisional biopsy			proceed to Question 114a, otherwise, skip to Question 115.
	procurement	☐ Fine needle aspira	tion		question 113.
		☐ Punch biopsy			
		☐ Other (specify)			
114a	Other method of	(1 //		6587390	If the procedure performed to obtain the tumor
	cancer sample				tissue is not included in the provided list, specify
	procurement				the procedure.
115	Number of days			3288495	Provide the number of days from the index date
	from index date to				to the date of the procedure that produced the
	date of				metastatic/recurrent tumor tissue submitted for
	metastatic/				HCMI.
	recurrent sample				
	procurement				
116	Metastatic/	☐ Bladder	☐ Ovary	6587394	Select the site from which the
	recurrent site	☐ Bone	☐ Ovary		metastatic/recurrent tissue used to develop the
		☐ Connective tissue	☐ Small intestine		model was derived.
		☐ Extrahepatic bile	☐ Thyroid gland		Note: If the metastatic/recurrent site is not listed,
		duct	☐ Uterus		proceed to Question 116a, otherwise, skip to Question 117.
		☐ Gallbladder	☐ Other site		question 117.
		Liver	(specify)		
		☐ Lymph node			
116a	Other metastatic/	☐ Abdomen	☐ Other ill-defined	6587395	If not included in the previous list, specify the
	recurrent site	☐ Accessory sinus	sites		site from which the metastatic/recurrent tissue
		☐ Adrenal gland	☐ Ovary		used to develop the model was derived.
		☐ Anus	☐ Palate		
		☐ Appendix	☐ Pancreas		
		☐ Bladder	☐ Penis		
		☐ Bone	☐ Peripheral nerves		
		☐ Breast	and autonomic		
		□ Connective,	nervous system of		
		subcutaneous	trunk		
		and other soft	☐ Peritoneum		
		tissues	☐ Pharynx		
		☐ Esophagus	☐ Pituitary gland		
		☐ Eye	☐ Prostate gland		
		☐ Gallbladder	☐ Rectosigmoid		
		☐ Gambiaddei	junction		
		☐ Head, face or	☐ Renal pelvis		
		· ·			
		neck	☐ Retroperitoneum		
		☐ Heart	☐ Skin	l	

V3.0				HCMI
Tissue Source Site (TSS) Name: Completed By:		Enrollment: Rare HCMI Identifier (ID3): Completion Date (MM/DD/YYYY):		
	☐ Kidney ☐ Larynx ☐ Lip	☐ Small intestine☐ Spinal cord☐ Spleen		

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		☐ Kidney		Small intestine		
		☐ Larynx		Spinal cord		
		☐ Lip		Spleen		
		☐ Liver		Stomach		
		☐ Lung		Testis		
		☐ Lymph node		Thymus		
		☐ Male genital		Thyroid gland		
		organs		Tongue		
		☐ Mediastinum		Tonsil		
				Trachea		
		☐ Meninges				
		☐ Mouth		Unknown primary		
		☐ Nasal cavity		Urinary system		
		☐ Nasopharynx		Uterus		
		☐ Nervous system		Vagina		
		☐ Oropharynx		Vulva		
117	Site of relapse	☐ Local			2002506	If the primary tumor relapsed, provide the site
		☐ Regional				of relapse.
		☐ Distant				
		☐ Not applicable				
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				3226275	Provide the ICD-O-3 histology code describing
	code					the morphology of the metastatic/recurrent
						tumor used to generate the model submitted to
						HCMI.
120	Maintenance				6119066	Provide the name(s) of the maintenance and/or
	and/or					consolidation therapy administered to the
	consolidation					patient prior to the collection of the
	therapy					metastatic/recurrent tissue used to develop the
	administered prior					model.
	to collection of					
	metastatic/					
	recurrent tissue					
121	Days to start of				5102411	Provide the number of days from the index date
	maintenance					to the date maintenance and/or consolidation
	and/or					therapy started.
	consolidation					
	therapy from					
	index date					
122	Days to last known				5102431	Provide the number of days from the index date
	administration					to the last known date of maintenance and/or
	date of					consolidation therapy.
1	maintenance					
1	and/or					
1	consolidation					
	therapy from					
	index date					
123	Is the patient still				6379568	Indicate whether the patient is still undergoing
	receiving					maintenance and/or consolidation therapy.
	treatment?	_				
124	Disease status	☐ No evidence of dis			2188290	Provide the disease status following
		☐ Progressive diseas	se			maintenance and/or consolidation therapy.
		☐ Stable disease				
Ī	1	☐ Unknown				

V3.0		
v 3.0	Enrollment: Rare	1
Tissue Source Site (TSS) Name:	HCMI Identifier (ID3):	1
Completed By:	Completion Date (MM/DD/YYYY):	

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Additional I	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 □ Ovary □ Connective tissue □ Small intestine □ Extrahepatic bile duct □ Thyroid gland □ Uterus □ Other site □ Liver (specify) □ Lymph node	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):	(X6)25	43		Tal
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Question	Question Text	Data Entry Options			CDE ID	Instruction Text
Question 133a	Question Text Other metastatic/ recurrent site	Data Entry Options 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		junction Renal pelvis Retroperitoneum Skin Small intestine	CDE ID 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	☐ Oropharynx ☐ Local ☐ Regional ☐ Distant ☐ Not applicable	<u>⊔</u>	Vulva	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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	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		5102411	Provide the number of days from the index date
	maintenance			to the date maintenance and/or consolidation
	and/or			therapy started.
	consolidation			
	therapy from			
	index date			
139	Days to last known		5102431	Provide the number of days from the index date
	administration			to the last known date of maintenance and/or
	date of			consolidation therapy.
	maintenance			
	and/or			
	consolidation			
	therapy from			
440	index date		6270560	
140	Is the patient still	☐ Yes	6379568	Indicate whether the patient is still undergoing
	receiving	□ No		maintenance and/or consolidation therapy.
	treatment?	Unknown	2.0000	
141	Disease status	☐ No evidence of disease	2188290	Provide the disease status following
		☐ Progressive disease☐ Stable disease		maintenance and/or consolidation therapy. Note: Proceed to Question 147.
				Note: Proceed to Question 147.
Motostatic	 /Recurrent Tumor Mod	Unknown		
142	METASTATIC/	<i>тентрогтаціон</i>	6594587	Diagram ravida a numbarta idantif.
142	RECURRENT model		6594587	Please provide a number to identify which biospecimen this is in the sequence.
	biospecimen			The first biospecimen should be number "1,"
	ordinal			the second should be number "2," etc.
	ordinal			the second should be humber 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		6584919	Please provide the BPC-generated ID
	(if available)			for this sample as it will appear on the
				Sample Submission Form transmitted
				to the BPC.
145	Model's		6586035	Enter the CMDC Sample ID of the METASTATIC/
145	METASTATIC/		0300033	RECURRENT tissue from which this model
	RECURRENT tumor			is derived.
	tissue			is derived.
	CMDC sample ID			
146	Model's		6584266	Enter the biospecimen ordinal
1-70	METASTATIC/RECU		0304200	of the METASTATIC/RECURRENT tissue from
	RRENT tumor			which this model is derived.
	tissue			Note: If submitting an additional
	biospecimen			Metastatic/Recurrent Tumor sample for model
	ordinal			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.
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	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 Mode	el Information (if appl	icable)	
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.
	ecimen Information	T			
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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Tissue Source Site (TSS) Name:	Enrollment: Rare HCMI Identifier (ID3):	
Completed By:	Completion Date (MM/DD/YYYY):	

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

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

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			3226275	Provide the ICD-O-3 histology code describing the
	code				morphology of the OTHER tissue used to
					generate the model submitted to HCMI.
					Note: Proceed to Question 163.
	OTHER biospecimen Ir	formation (if applicable	<u>e) </u>		
163	Are you				Indicate whether an additional OTHER tissue
	submitting an				sample (pre-malignant, non-malignant, or
	additional OTHER	Yes			dysplastic tissue, etc.) is being submitted for
	tissue sample?	□ No			HCMI for this case.
					Note: If yes, proceed to Question 164. If no, proceed to Question 174.
164	OTHER tissue			6584267	Please provide a number to identify which
	biospecimen				biospecimen this is in the sequence.
	ordinal				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			6584919	Please provide the BPC-generated ID for this
	(if available)				sample as it will appear on the Sample
167	OTLIED tiesus			5432521	Submission Form transmitted to the BPC.
167	OTHER tissue	☐ Cryopreserved	☐ Frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular
	sample	☐ FFPE	□ OCT		
	preservation method	☐ Fresh	☐ Snap frozen		characterization.
168	Other method of	☐ Tumor resection		6587398	Provide the procedure performed to obtain the
	cancer sample	☐ Biopsy	☐ Fine needle		OTHER tissue.
	procurement	☐ Core needle	aspiration		Note: If the method of procurement is not listed,
	·	biopsy	Punch biopsy		proceed to Question 168a, otherwise, skip to Question
		☐ Incisional biopsy	☐ Other (specify)		169.
168a	Specify method of	_ meisienai siepsy		6587399	Specify the procedure performed to obtain the
	OTHER tissue				OTHER tissue.
	sample				
	procurement				
169	Number of days			3288495	Provide the number of days from the index date
	from index date to				to the date of the procedure that produced the
	date of OTHER				OTHER tissue tissue submitted for HCMI.
	sample				
	procurement				
170	Tissue type	☐ Non-malignant		64784	Indicate the OTHER tissue type.
		☐ Other (specify)			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	☐ Bladder	□ Ovary	6696813	Select the site from which the OTHER tissue
	OTHER tissue	☐ Bone	☐ Skin		used to develop the model was derived.
		☐ Connective	☐ Small intestine		Note: If the OTHER tissue site is not listed, proceed to
		tissue	☐ Thyroid gland		Question 171a, otherwise, skip to Question 172.
		☐ Extrahepatic bile	☐ Uterus		
		duct	☐ Other site		
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Tissue Source Site (TSS) Name:Completed By:	Enrollment: Rare HCMI Identifier (ID3): Completion Date (MM/DD/YYYY):	

Question	Question Text	Data Entry Options			CDE ID	Instruction Text
171a	Specify anatomic	☐ Abdomen		Peritoneum	6584916	Specify the site of OTHER tissue, if not in the
	site of OTHER	☐ Accessory sinus		Pharynx Pituitary		previous list.
	tissue	☐ Adrenal gland		gland		
		☐ Anus		Prostate gland		
		☐ Appendix		Rectosigmoid		
		□ Bladder		junction		
		☐ Bone		Renal pelvis		
		☐ Breast		Retroperiton-		
		☐ Connective,	_	eum		
		subcutaneous		Skin		
		and other soft		Small intestine		
		tissues		Spinal cord		
		☐ Esophagus		Spleen		
		☐ Eye		Stomach		
		☐ Gallbladder		Testis		
		☐ Gambiadder		Thymus		
				-		
		☐ Head, face or		Thyroid gland		
		neck		Tongue		
		☐ Heart		Tonsil		
		Ovary		Trachea		
		☐ Palate	Ц	Unknown		
		☐ Pancreas	_	primary		
		☐ Penis		Urinary system		
		☐ Peripheral		Uterus		
		nerves and		Vagina		
		autonomic		Vulva		
		nervous system				
470	100.40	of trunk			2225227	D : 1 10 10 10 1 5 1 0 0 1 0 0 1
172	ICD-10 code				3226287	Provide the ICD-10 code for the OTHER tissue
173	ICD-O-3 histology				3226275	used to generate the model submitted to HCMI. Provide the ICD-O-3 histology code describing the
1/3	code				3220273	morphology of the OTHER tissue used to
	Code					generate the model submitted to HCMI.
						Note: Proceed to Question 174.
	Model Information	1				
174	OTHER tissue				6594590	Please provide a number to identify which
	model					biospecimen this is in the sequence.
	biospecimen					Note: The first biospecimen should be number "1," the second should be number "2," etc.
175	ordinal				6506036	·
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				6584919	Please provide the BPC-generated ID for this
1,0	(if available)				3304313	sample as it will appear on the Sample
						Submission Form transmitted to the BPC.
177	Model's OTHER				6586035	Enter the CMDC Sample ID of the OTHER
-	tissue CMDC					tissue from which this model is derived.
	sample ID					
178	Model's OTHER				6584267	Enter the biospecimen ordinal of the OTHER
	tissue					tissue from which this model is derived.
	biospecimen					
	ordinal					

V3.0		HCMI	
	Enrollment: Rare		4
Tissue Source Site (TSS) Name:	HCMI Identifier (ID3):		K
Completed By:	Completion Date (MM/DD/YYYY):		

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Additional	Other Tissue Model In	formation (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.

V3.0		HCMI	
	Enrollment: Rare		
Tissue Source Site (TSS) Name:	HCMI Identifier (ID3):	120	
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 Clin	ical 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 (>10 mutations/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.

V3.0		HCIVII P
	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 Mu	tational Analysis		
8	Was mutation analysis performed for any of the following genes?	☐ ALK ☐ GNAS ☐ PIK3CA ☐ BRAF ☐ H3 K27 ☐ PTEN ☐ CDKN2A ☐ IDH1/2 ☐ TP53 ☐ EGFR ☐ KRAS		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 19.
9	Was a mutation in ALK identified?	☐ Yes ☐ No	3774202	Indicate whether a mutation in ALK was identified. <i>Note: If yes, proceed to Question 9a.</i>
9a	If ALK mutation identified, which one?	☐ F1174L ☐ F1174C ☐ K1062M ☐ F1174V ☐ R1275Q ☐ F1245L ☐ T1087I ☐ 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 □ V600R □ V600D □ K601E □ V600K □ 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 □ L130Q □ V51I □ H83P □ H83Y □ D108H □ 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 □ Exon 19 □ T790M deletion □ C797S □ Exon 20 □ L858R insertion □ L861Q □ 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.

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Tissue Source Site (TSS) Name:	HCMI Identifier (ID3):	To your	48
Completed By:	Completion Date (MM/DD/YYYY):	a b	36

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 t□ Whole exome seq□ 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	o		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.

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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 □ G245S □ R273C (specify)	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 Pro	tein Expression Information	•	
20	Was IHC performed in any of the following proteins?	□ BRAF V600E □ ER □ H3 K27M □ HER2 □ IDH1 R132H □ MLH1 □ MSH2 □ MSH2 □ MSH2 □ MSH2		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 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).

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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).