

Enrollment: Melanoma

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



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

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	<input type="checkbox"/> Initial pathologic diagnosis <input type="checkbox"/> Sample procurement <input type="checkbox"/> 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	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> 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	<input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian or other Pacific Islander <input type="checkbox"/> White <input type="checkbox"/> Unknown <input type="checkbox"/> 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	<input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Unknown <input type="checkbox"/> 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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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	<input type="checkbox"/> Same <input type="checkbox"/> Different <input type="checkbox"/> None <input type="checkbox"/> 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	<input type="checkbox"/> Lifelong non-smoker (<100 cigarettes smoked in a lifetime) <input type="checkbox"/> Current smoker (includes daily and non-daily smokers) <input type="checkbox"/> Current reformed smoker (duration not specified) <input type="checkbox"/> Current reformed smoker for >15 years <input type="checkbox"/> Current reformed smoker for ≤15 years	2181650	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories.
15	Metastasis at diagnosis assessment status	<input type="checkbox"/> Metastatic <input type="checkbox"/> Non-metastatic (confirmed) <input type="checkbox"/> Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor. Note: If metastatic at diagnosis, proceed to Question 16, otherwise, skip to Question 17.
16	Metastatic site(s) at diagnosis	<input type="checkbox"/> Brain <input type="checkbox"/> Lung <input type="checkbox"/> Skin/subcutaneous <input type="checkbox"/> Other (specify)	3029815	Indicate the site(s) of metastasis at the time of diagnosis of the primary tumor. Note: If the anatomic site of tumor tissue is not listed, proceed to Question 16a, otherwise, skip to Question 17.
16b	Specify metastatic site(s)	_____	3128033	If the site of metastasis is not included on the provided list, specify the site of metastasis.
Biospecimen Information				
17	Tissue sample type(s) collected for HCMI for this case	<input type="checkbox"/> Normal tissue <input type="checkbox"/> Primary tumor <input type="checkbox"/> Metastatic <input type="checkbox"/> Recurrent <input type="checkbox"/> Other tissue	2006911	Please select all the tissue sample types submitted for HCMI with this case.
18	Number of NORMAL tissues biospecimens collected for HCMI for this case	_____	6584256	Please provide the number of normal tissue specimens obtained for HCMI for this case. Note: This number is expected to be 1.
19	Number of PRIMARY cancer tissue biospecimens collected for HCMI model development for this case	_____	6584257	Please provide the number of primary tumor specimens obtained for HCMI for this case. Note: A single primary tumor biospecimen obtained that is portioned for both sequencing and model generation counts as 1 single primary tumor specimen. This number is expected to be 1.
20	Number of METASTATIC/RECURRENT cancer tissue biospecimens collected for HCMI model development for this case	_____	6584258	Please provide the number of metastatic and/or recurrent cancer biospecimens collected for HCMI for this case. Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

Enrollment: Melanoma

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



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

Enrollment: Melanoma

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



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