Enrollment: Neuroblastoma

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

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

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

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

Enrollment: Neuroblastoma

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

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

Enrollment: Neuroblastoma

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

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

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

Enrollment: Neuroblastoma

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

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

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

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

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

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

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

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

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

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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
133a	Other ALK mutation	_____	6101680	If the ALK mutation identified is not included in the provided list, specify the ALK mutation identified.
Metastatic/Recurrent Tumor Model Information				
134	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
135	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
136	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
137	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
138	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Additional Metastatic/Recurrent Biospecimen Tumor Model Information (if applicable)				
139	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
140	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
141	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
142	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
143	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Other Biospecimen Information				
144	Are you submitting an OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an OTHER tissue sample (e.g. pre-malignant, non-malignant, or dysplastic tissue, etc.) was collected for HCMI for this case. ***Note: If yes, proceed to Question 145.***

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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
145	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
146	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
147	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
148	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
149	Method of OTHER tissue sample procurement	☐ Core needle biopsy ☐ Excisional biopsy ☐ Fine needle aspiration ☐ Incisional biopsy ☐ Tumor resection ☐ Other method, specify	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 149a, otherwise, skip to Question 150.***
149a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
150	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
151	Tissue type	☐ Pre-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 151a, otherwise, skip to Question 152.***
151a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
152	Anatomic site of OTHER tissue	☐ Abdominal/non-adrenal ☐ Adrenal ☐ Ascites ☐ Bone ☐ Bone marrow ☐ Extra-adrenal ☐ Lung ☐ Lymph node(s) regional ☐ Lymph node(s) distant ☐ Neck ☐ Posterior mediastinum ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 152a, otherwise, skip to Question 153.***
152a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.
153	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
154	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.

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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Additional OTHER biospecimen Information (if applicable)				
155	Are you submitting an additional OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an additional OTHER tissue sample (pre-malignant, non-malignant, or dysplastic tissue, etc.) is being submitted for HCMI for this case. ***Note: If yes, proceed to Question 156, otherwise, skip to Question 166.***
156	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
157	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
158	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
159	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
160	Method of OTHER tissue sample procurement	☐ Core needle biopsy ☐ Excisional biopsy ☐ Fine needle aspiration ☐ Incisional biopsy ☐ Tumor resection ☐ Other method, specify	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 160a, otherwise, skip to Question 161.***
160a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
161	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
162	Tissue type	☐ Pre-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 162a, otherwise, skip to Question 163.***
162a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
163	Anatomic site of OTHER tissue	☐ Abdominal/non-adrenal ☐ Adrenal ☐ Ascites ☐ Bone ☐ Bone marrow ☐ Extra-adrenal ☐ Lung ☐ Lymph node(s) regional ☐ Lymph node(s) distant ☐ Neck ☐ Posterior mediastinum ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 163a, otherwise, skip to Question 164.***
163a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.

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Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
164	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
165	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Other Tissue Model Information				
166	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
167	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
168	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
169	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
170	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.
Additional Other Tissue Model Information (if applicable)				
171	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
172	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
173	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
174	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.