Enrollment: Rhabdomyosarcoma

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

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

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

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
9	ICD-10 code for model tumor	☐ C49.0 ☐ C49.1 ☐ C49.2 ☐ C49.3 ☐ C49.4 ☐ C49.5 ☐ C49.6 ☐ C49.8 ☐ C49.9 ☐ C77.9 ☐ C78.0 ☐ C79.5 ☐ Other (specify)	3226287	Provide the ICD-10 code for the tumor used to generate the model submitted to HCMI. ***Note: If the ICD-10 code is not listed, proceed to Question 9a, otherwise, skip to Question 10.***
9a	Other ICD-10 code	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.
10	Tumor tissue type	☐ Premalignant ☐ Primary ☐ Recurrent ☐ Metastatic ☐ Additional primary ☐ NOS	3288124	Provide the tumor tissue type for the biospecimen used to produce the model for the HCMI. ***Note: If 'Metastatic' is selected, continue to answer through Question 18. If the tissue is not 'Metastatic', skip to Question 19.***
Metastatic Model Information *(only complete Questions 11-18 if 'Metastatic' was selected in Question 10)*				
11	Age at diagnosis of metastasis	_____	6032752	Provide the age (in days) of the patient when diagnosed with metastatic disease. If the patient's age is greater than 32,507 days (89 years), please enter 32,507.
12	Number of days from index date to date of diagnosis of metastasis	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic disease.
13	Metastatic site	☐ Lung ☐ Bone ☐ Bone marrow ☐ Lymph node(s) ☐ Lymph node(s) - distant ☐ Other (specify)	6119068	Select the site from which the metastatic tissue used to develop the model was derived. ***Note: If the metastatic site is not listed, proceed to Question 13a, otherwise, skip to Question 14.***
13a	Other metastatic site	_____	3128033	If not included in the previous list, specify the site from which the metastatic tissue used to develop the model was derived.
14	Maintenance and/or consolidation therapy administered prior to collection of metastatic tissue	_____	6119066	If applicable, provide the name of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic tissue used to develop the model. ***Note: If maintenance and/or consolidation therapy was not administered, skip to Question 19.***
15	Days from index date to start of maintenance and/or consolidation therapy	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
16	Days from index date to last known date of maintenance and/or consolidation therapy treatment	_____	65167	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.

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

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Primary Tumor Diagnosis Information				
28	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.
29	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. If the patient's age is greater than 32,507 days (89 years), please enter 32,507.
30	Morphology	☐ 8900/3 (Rhabdomyosarcoma, NOS) ☐ 8901/3 (Pleomorphic rhabdomyosarcoma, NOS) ☐ 8902/3 (Mixed type rhabdomyosarcoma) ☐ 8910/3 (Embryonal rhabdomyosarcoma, NOS) ☐ 8912/3 (spindle cell rhabdomyosarcoma) ☐ 8920/3 (Alveolar rhabdomyosarcoma) ☐ 8921/3 (Rhabdomyosarcoma with ganglionic differentiation) ☐ Other (specify)	3226275	Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor. ***Note: If the morphology is not listed, proceed to Question 30a, otherwise, skip to Question 31.***
30a	Other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.
31	Tissue or organ of origin	☐ Abdominal cavity ☐ Bladder ☐ Head and neck ☐ Limb ☐ Prostate ☐ Retroperitoneum ☐ Testes ☐ Other (specify)	3427536	Using the patient's pathology/laboratory report, select the primary site of the disease. ***Note: If the tissue or organ of origin is not listed, proceed to Question 31a, otherwise, skip to Question 32.***

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
31a	Other tissue or organ of origin	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	3427536	If the primary site of the disease is not included on the previous list, select the primary site of the disease.
32	Histological type	_____	3081932	Provide the traditional surgical pathology text description of the histological tumor type.
33	Histological subtype	☐ Alveolar ☐ Embryonal ☐ Other ☐ Unknown	4214626	Using the patient's pathology/laboratory report, select the histological subtype of the primary tumor.
34	Prior malignancy (of the same cancer type)	☐ Yes ☐ No ☐ Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
35	Prior malignancy (other cancer type)	☐ Yes ☐ No ☐ Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.
36	Tumor stage	☐ 1: Favorable site ☐ 2: Unfavorable site; <= 5cm; no regional node involvement ☐ 3: Unfavorable site; > 5 cm; and/or regional node involvement ☐ 4: Metastatic disease	5162089	Provide the stage of the tumor using the IRS (Intergroup Rhabdomyosarcoma Study) staging guidelines.

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
37	Metastasis at diagnosis assessment status	☐ Metastatic ☐ Non-metastatic (confirmed) ☐ Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor.
38	Metastatic site(s) at diagnosis	☐ Lung ☐ Bone ☐ Bone marrow ☐ Lymph node(s) ☐ Lymph node(s) - distant ☐ Other (specify)	3029815	Indicate all the site(s) of metastasis at the time of diagnosis of the primary tumor. ***Note: If the metastatic site(s) is not listed, proceed to Question 38a, otherwise, skip to Question 39.***
38a	Specify metastatic site(s)	_____	3128033	If the site(s) of metastasis at the time of diagnosis of the primary tumor is not included in the provided list, specify the site(s).
39	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, select all sites of relapse. ***Note: If the primary tumor did not relapse, select 'Not applicable'.***
Prognostic/Predictive/Lifestyle Features for Tumor Prognosis or Responsiveness to Treatment				
40	Intergroup Rhabdomyo-sarcoma Study group	☐ I: Tumor completely removed ☐ IIa: Microscopic residual; margin positive; nodes negative ☐ IIb: Microscopic residual; margin negative; nodes positive (completely resected) ☐ IIc: Microscopic residual; margin positive; nodes positive (completely resected) ☐ III: Gross residual ☐ IV: Metastasis ☐ Unknown	4925522	Indicate the post-surgical procedure neoplasm status by IRS group.
41	Children's Oncology Group risk group	☐ High ☐ Intermediate ☐ Low ☐ Unknown	2963688	Indicate the soft-tissue sarcoma histologic grade.
42	Was tumor confined to organ of origin?	☐ Yes ☐ No ☐ Unknown ☐ Not applicable	4925494	Indicate whether the tumor was confined to the organ of origin. If T1 (confined to anatomic site of origin), please select "Yes." If T2 (extension and/or fixative to surrounding tissue), please select "No."
43	Anaplasia	☐ Absent ☐ Focal ☐ Diffuse ☐ Unknown	4925534	Indicate whether anaplasia was present in the primary tumor.
44	Maximum diameter (cm) of primary tumor if identifiable at initial diagnosis	_____	62602	Provide the length of the largest diameter of the primary tumor, in centimeters.
45	FOXO1 fusion result	☐ FOXO1 rearranged (FOXO1 with unknown partner) ☐ PAX3 – FOXO1 translocation ☐ PAX7 – FOXO1 translocation ☐ Other FOXO1 translocation (FOXO1 with known partner) ☐ No FOXO1 rearrangement ☐ Indeterminate	5159111	If the histologic subtype of the primary tumor is alveolar, select the FOXO1 gene fusion, if identified.

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Treatment Information				
46	History of neoadjuvant treatment	☐ No ☐ Yes; radiation prior to resection ☐ Yes; pharmaceutical treatment prior to resection ☐ Yes; both radiation and pharmaceutical treatment prior to resection ☐ Unknown	3382737	Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment. ***Note: Radiation therapy is addressed in Questions 54-55. Pharmaceutical therapy is addressed in Questions 47-53.***
47	Neoadjuvant chemotherapy type	☐ Cytotoxic chemotherapy ☐ Hormonal ☐ Immunotherapy (cellular and immune checkpoint) ☐ Targeted therapy (small molecule inhibitors and targeted antibodies) ☐ Not applicable	5832928	Select all neoadjuvant chemotherapy types that were administered to the patient. ***Note: Cytotoxic chemotherapy is addressed in Questions 48-49. Immunotherapy is addressed in Questions 50-51. Targeted therapy is addressed in Questions 52-53.***
48	Neoadjuvant chemotherapeutic regimen	☐ Doxorubicin ☐ Ifosfamide and Etoposide ☐ Irinotecan ☐ Temozolomide ☐ Vincristine ☐ Vinorelbine ☐ Vincristine, actinomycin-D, cyclophosphamide (VAC) ☐ Vincristine, doxorubicin, cyclophosphamide, ifosfamide, etoposide (VDC/IE) ☐ Vincristine, actinomycin-D, cyclophosphamide, vincristine, irinotecan (VAC/VI) ☐ Ifosfamide, carboplatin, etoposide (ICE) ☐ Vincristine, irinotecan, temozolomide (VIT) ☐ High-dose methotrexate, doxorubicin, cisplatin (MAP) ☐ Other (specify) ☐ Chemotherapy not given	2853313	Select all chemotherapeutics used for neoadjuvant therapy. ***Note: If neoadjuvant chemotherapy was not given, skip to Question 50. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 48a, otherwise, skip to Question 49.***
48a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapy.
49	Days to neoadjuvant chemotherapy treatment from index date	_____	5102411	Provide the number of days from index date to the date of treatment with neoadjuvant chemotherapy.
50	Immunotherapy name, specify	_____	2185614	Specify the name of the immunotherapy administered. ***Note: If immunotherapy was not given, skip to Question 52.***
51	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
52	Targeted therapy	☐ Temsirolimus ☐ Other (specify)	6005154	Select the targeted therapy administered to the patient. ***Note: If targeted therapy was not given, skip to Question 53. If the targeted therapy is not listed, proceed to Question 52a, otherwise, skip to Question 53.***

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
52a	Other targeted therapy	_____	4308476	If the targeted therapy is not included in the provided list, specify targeted therapy.
53	Days to targeted therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with targeted therapy.
54	Radiation therapy administered type	☐ 2D conventional ☐ 3D conformal ☐ Brachytherapy HDR ☐ Brachytherapy LDR ☐ IMRT ☐ Proton Beam ☐ Stereotactic Body RT ☐ Stereotactic Radiosurgery ☐ WBRT ☐ Other (specify) ☐ Unspecified ☐ Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. ***Note: If radiation therapy was not administered, skip the remaining questions. If the radiation therapy is not listed, proceed to Question 53a, otherwise, skip to Question 54.***
54a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
55	Days to radiation treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with radiation therapy.