Enrollment: Pediatric Liver

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	☐ Ascites ☐ Bone ☐ Brain ☐ Liver ☐ Lung ☐ Lymph node ☐ 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	☐ C22.0 ☐ C22.1 ☐ C22.2 ☐ C22.3 ☐ C22.4 ☐ C22.7 ☐ C22.8 ☐ C22.9 ☐ C77.9 ☐ C78.0 ☐ C79.3 ☐ 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 ☐ Brain ☐ Bone ☐ 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	Tobacco 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	☐ 8170/3 (Hepatocellular carcinoma, NOS) ☐ 8171/3 (Hepatocellular carcinoma, fibrolamellar) ☐ 8970/3 (Hepatoblastoma) ☐ 8991/3 (Embryonal sarcoma) ☐ 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	☐ Liver ☐ 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.***
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.

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
32	Histological type	_____	3294805	Provide the traditional surgical pathology text description of the histological tumor type.
33	If hepatoblastoma, specify histology	☐ Fetal/embryonal ☐ Mesenchymal/macrotrabecular ☐ Mixed epithelial ☐ Small cell undifferentiated ☐ Well differentiated fetal ☐ Unknown ☐ Not applicable	4908981	If the liver cancer is hepatoblastoma, specify the histology.
34	If hepatocellular carcinoma, specify histology	☐ Fibrolamellar ☐ Hepatocellular NOS ☐ Unknown ☐ Not applicable	4908996	If the liver cancer is hepatocellular carcinoma, specify the histology.
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	Tumor stage	☐ I ☐ II ☐ III ☐ IV	6013618	Provide the stage of the tumor using the PRETEXT staging system.
38	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.
39	Metastatic site(s) at diagnosis	☐ Lung ☐ Brain ☐ Bone ☐ 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 39a, otherwise, skip to Question 40.***
39a	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).
40	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				
41	Premature birth (born <37 weeks gestation)?	☐ Yes ☐ No ☐ Unknown	6010765	Indicate whether the patient was born at less than 37 weeks gestation. ***Note: If not born prematurely, skip to Question 43.***
42	Weeks gestation at birth	_____	2737369	Specify the number of weeks of gestation at which the patient was born.
43	Genetic predisposition mutation known?	☐ Yes ☐ No ☐ Unknown	2665140	Indicate whether the patient has a known genetic predisposition mutation. ***Note: If the genetic predisposition mutation is not known, skip to Question 45.***
44	Genetic predisposition mutation	☐ APC ☐ P53 ☐ Other (specify)	6010766	Select the patient's known genetic predisposition mutation. ***Note: If the mutation is not listed, proceed to Question 44a, otherwise, skip to Question 45.***

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
44a	Other genetic predisposition mutation	_____	2772026	If the patient's genetic predisposition mutation is not included on the previous list, specify the patient's other known genetic predisposition mutation.
45	Does the patient have genetic syndrome(s)?	☐ Yes ☐ No ☐ Unknown	4917534	Indicate whether the patient has any genetic syndromes. ***Note: If the patient does not have a genetic syndrome, skip to Question 47.***
46	Syndrome(s) diagnosed	☐ Alpha-1 antitrypsin ☐ Glycogen storage disease ☐ Biliary abnormality ☐ Tyrosinemia ☐ Cirrhosis without an underlying etiology ☐ Beckwidth-Wiedemann ☐ Other (specify)	6013458	Select the patient's diagnosed genetic syndrome(s). ***Note: If the syndrome is not listed, proceed to Question 46a, otherwise, skip to Question 47.***
46a	Other syndrome diagnosed	_____	64158	If the patient's genetic syndrome is not included in the provided list, please specify the patient's other genetic syndrome.
47	Infection history?	☐ Yes ☐ No ☐ Unknown	2816879	Indicate whether the patient has a history of relevant infectious disease. ***Note: If the patient does not have relevant infection history, skip to Question 49.***
48	Name of relevant infectious disease	☐ Hepatitis A ☐ Hepatitis B ☐ Hepatitis C	3233642	Indicate the name of the relevant infectious disease.
49	Upper limit of normal range for the Alpha-Fetoprotein level	_____	2932064	Provide the upper limit of normal for alpha-fetoprotein in ng/mL.
50	Lower limit of normal range for the Alpha-Fetoprotein level	_____	3171861	Provide the lower limit of normal for alpha-fetoprotein in ng/mL.
51	Alpha-Fetoprotein level (0-10 million ng/mL) at diagnosis	_____	2932074	Provide the numerical laboratory result for alpha-fetoprotein in ng/mL.
Treatment Information				
52	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 60-61. Pharmaceutical therapy is addressed in Questions 53-59.***
53	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 54-55. Immunotherapy is addressed in Questions 56-57. Targeted therapy is addressed in Questions 58-59.***

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54	Neoadjuvant chemotherapeutic regimen	☐ 5-fluorouracil ☐ Carboplatin ☐ Cisplatin ☐ Doxorubicin ☐ Etoposide ☐ Ifosfamide ☐ Pirarubicin ☐ 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 49. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 47a, otherwise, skip to Question 48.***
54a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapy.
55	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.
56	Immunotherapy name, specify	_____	2185614	Specify the name of the immunotherapy administered. ***Note: If immunotherapy was not given, skip to Question 51.***
57	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
58	Targeted therapy	☐ Sorafenib ☐ Other (specify)	6010754	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 58a, otherwise, skip to Question 59.***
58a	Other targeted therapy	_____	4308476	If the targeted therapy is not included in the provided list, specify targeted therapy.
59	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.

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60	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 60a, otherwise, skip to Question 61.***
60a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
61	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.