
## Enrollment: Osteosarcoma

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<br>☐ Sample procurement<br>☐ 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<br>☐ Buccal cells<br>☐ Buffy coat<br>☐ Lymphocytes<br>☐ Extracted DNA from blood<br>☐ Extracted DNA from saliva<br>☐ Extracted DNA from buccal cells<br>☐ Extracted DNA from normal tissue<br>☐ FFPE non-neoplastic tissue<br>☐ 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<br>☐ Fresh<br>☐ OCT<br>☐ 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<br>☐ Bone<br>☐ Lower extremity<br>☐ Lung<br>☐ Lymph node<br>☐ Mediastinum<br>☐ Pelvis<br>☐ Pleura<br>☐ Spine<br>☐ Upper extremity<br>☐ Other (specify) | 6005095 | Indicate the anatomic site of the tumor tissue used to generate the model for the HCMI.<br>***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<br>☐ Excisional biopsy<br>☐ Fine needle aspiration<br>☐ Incisional biopsy<br>☐ Tumor resection<br>☐ Other (specify) | 3103514 | Indicate the procedure performed to obtain the tumor tissue used to generate the model for HCMI.<br>***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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| 9 | ICD-10 code for model tumor | ☐ C40.0 ☐ C41.3<br>☐ C40.1 ☐ C41.4<br>☐ C40.2 ☐ C41.8<br>☐ C40.3 ☐ C41.9<br>☐ C40.8 ☐ C77.9<br>☐ C40.9 ☐ C78.0<br>☐ C41.0 ☐ C78.1<br>☐ C41.1 ☐ C79.5<br>☐ C41.2 ☐ Other (specify) | 3226287 | Provide the ICD-10 code for the tumor used to generate the model submitted to HCMI.<br>***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<br>☐ Primary<br>☐ Recurrent<br>☐ Metastatic<br>☐ Additional primary<br>☐ NOS | 3288124 | Provide the tumor tissue type for the biospecimen used to produce the model for the HCMI.<br>***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<br>☐ Bone<br>☐ Mediastinum<br>☐ Lymph node (not mediastinum)<br>☐ Other (specify) | 6119068 | Select the site from which the metastatic tissue used to develop the model was derived.<br>***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.<br>***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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| 17 | Is the patient still receiving treatment? | ☐ Yes<br>☐ No<br>☐ Unknown | 6379568 | Indicate whether the patient is still undergoing treatment. |
| 18 | Disease status | ☐ No evidence of disease<br>☐ Progressive disease<br>☐ Stable disease<br>☐ Unknown | 2188290 | Provide the disease status following maintenance and/or consolidation therapy. |
| ***Patient Information*** | | | | |
| 19 | Gender | ☐ Male<br>☐ Female<br>☐ 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<br>☐ Asian<br>☐ Black or African American<br>☐ Native Hawaiian or other Pacific Islander<br>☐ White<br>☐ Unknown<br>☐ Not allowed to collect | 2192199 | Provide the patient's race using the defined categories.<br>**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.<br>**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.<br>**Black or African American:** A person having origins in any of the black racial groups of Africa.<br>**Native Hawaiian or other Pacific Islander:** A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island.<br>**White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa. |
| 24 | Ethnicity | ☐ Hispanic or Latino<br>☐ Not Hispanic or Latino<br>☐ Unknown<br>☐ Not allowed to collect | 2192217 | Provide the patient's ethnicity using the defined categories.<br>**Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race.<br>**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<br>☐ Different<br>☐ None<br>☐ 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)<br>☐ Current smoker (includes daily and non-daily smokers)<br>☐ Current reformed smoker (duration not specified)<br>☐ Current reformed smoker for >15 years<br>☐ 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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|---|---|---|---|---|
| ***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 | ☐ 9180/3 (Osteosarcoma, NOS)<br>☐ 9181/3 (Chondroblastic osteosarcoma)<br>☐ 9182/3 (Fibroblastic osteosarcoma)<br>☐ 9183/3 (Telangiectatic osteosarcoma)<br>☐ 9184/3 (Osteosarcoma in Paget disease of bone)<br>☐ 9185/3 (Small cell osteosarcoma)<br>☐ 9186/3 (Central osteosarcoma)<br>☐ 9187/3 (Intraosseous well differentiated osteosarcoma)<br>☐ 9192/3 (Parosteal osteosarcoma)<br>☐ 9193/3 (Periosteal osteosarcoma)<br>☐ 9194/3 (High grade surface osteosarcoma)<br>☐ 9195/3 (Intracortical osteosarcoma)<br>☐ Other (specify) | 3226275 | Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor.<br>***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 | ☐ Limb<br>☐ Pelvis<br>☐ Spine<br>☐ Other (specify) | 3427536 | Using the patient's pathology/laboratory report, select the primary site of the disease.<br>***Note: If the tissue or organ of origin is not listed, proceed to Question 31a, otherwise, skip to Question 32.*** |


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| 31a | Other tissue or organ of origin | ☐ Abdomen<br>☐ Accessory sinus<br>☐ Adrenal gland<br>☐ Anus<br>☐ Appendix<br>☐ Bladder<br>☐ Bone<br>☐ Breast<br>☐ Connective, subcutaneous and other soft tissues<br>☐ Esophagus<br>☐ Eye<br>☐ Gallbladder<br>☐ Gum<br>☐ Head, face or neck<br>☐ Heart<br>☐ Kidney<br>☐ Larynx<br>☐ Lip<br>☐ Liver<br>☐ Lung<br>☐ Lymph node<br>☐ Male genital organs<br>☐ Mediastinum<br>☐ Meninges<br>☐ Mouth<br>☐ Nasal cavity<br>☐ Nasopharynx<br>☐ Nervous system<br>☐ Oropharynx<br>☐ Other ill-defined sites<br>☐ Ovary<br>☐ Palate<br>☐ Pancreas<br>☐ Penis<br>☐ Peripheral nerves and autonomic nervous system of trunk<br>☐ Peritoneum<br>☐ Pharynx<br>☐ Pituitary gland<br>☐ Prostate gland<br>☐ Rectosigmoid junction<br>☐ Renal pelvis<br>☐ Retroperitoneum<br>☐ Skin<br>☐ Small intestine<br>☐ Spinal cord<br>☐ Spleen<br>☐ Stomach<br>☐ Testis<br>☐ Thymus<br>☐ Thyroid gland<br>☐ Tongue<br>☐ Tonsil<br>☐ Trachea<br>☐ Unknown primary<br>☐ Urinary system<br>☐ Uterus<br>☐ Vagina<br>☐ 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 | ☐ Malignant bone neoplasm<br>☐ Other (specify) | 3081932 | Provide the traditional surgical pathology text description of the histological tumor type. ***Note: If the histological type is not listed, proceed to Question 32a, otherwise, skip to Question 33.*** |
| 32a | 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. |
| 33 | Histological subtype | ☐ Osteoblastic<br>☐ Chondroblastic<br>☐ Fibroblastic<br>☐ Telangiectatic<br>☐ 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<br>☐ No<br>☐ Unknown | 5832924 | Indicate whether the patient has a history of prior malignancy of the same cancer type. |
| 35 | Prior malignancy (other cancer type) | ☐ Yes<br>☐ No<br>☐ Unknown | 5878828 | Indicate whether the patient has a history of prior malignancy of a different cancer type. |


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| 36 | Osteosarcoma stage | ☐ Localized<br>☐ Certain metastatic<br>☐ Possible metastatic<br>☐ Unknown | 4928400 | Provide the stage of the tumor using the COG Osteosarcoma staging guidelines. |
| 37 | Primary tumor size (largest dimension, in cm) | _____ | 64215 | Provide the length of the largest dimension of the primary tumor, in centimeters. |
| 38 | Percent tumor necrosis | _____ | 2841237 | Indicate the percent necrosis of the primary tumor at the time of resection. |
| 39 | Metastasis at diagnosis assessment status | ☐ Metastatic<br>☐ Non-metastatic (confirmed)<br>☐ Non-metastatic (unconfirmed) | 3438571 | Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor. |
| 40 | Metastatic site(s) at diagnosis | ☐ Lung<br>☐ Bone<br>☐ Mediastinum<br>☐ Lymph node (not mediastinum)<br>☐ Other (specify) | 4616511 | Indicate all the site(s) of metastasis at the time of diagnosis of the primary tumor.<br>***Note: If the metastatic site(s) is not listed, proceed to Question 39a, otherwise, skip to Question 40.*** |
| 40a | 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). |
| 41 | Site of relapse | ☐ Local<br>☐ Regional<br>☐ Distant<br>☐ Not applicable | 2002506 | If the primary tumor relapsed, select all sites of relapse.<br>***Note: If the primary tumor did not relapse, select 'Not applicable'.*** |
| ***Prognostic/Predictive/Lifestyle Features for Tumor Prognosis or Responsiveness to Treatment*** | | | | |
| 42 | Enneking/MSTS stage; Grade | ☐ Low grade (G1)<br>☐ High grade (G2)<br>☐ Unknown | 6003955 | Provide the grade of the primary tumor according to the Enneking Musculoskeletal Tumor Society (MSTS) staging system. |
| 43 | Enneking/MSTS stage; Tumor | ☐ Intracompartmental (T1)<br>☐ Extracompartmental (T2)<br>☐ Unknown | 6003957 | Provide the tumor stage of the primary tumor according to the Enneking Musculoskeletal Tumor Society (MSTS) staging system. |
| 44 | Enneking/MSTS stage; Metastasis | ☐ No metastasis (M0)<br>☐ Regional or distant metastasis (M1)<br>☐ Unknown | 6003958 | Provide the metastatic stage according to the Enneking Musculoskeletal Tumor Society (MSTS) staging system. |
| ***Treatment Information*** | | | | |
| 45 | History of neoadjuvant treatment | ☐ No<br>☐ Yes; radiation prior to resection<br>☐ Yes; pharmaceutical treatment prior to resection<br>☐ Yes; both radiation and pharmaceutical treatment prior to resection<br>☐ Unknown | 3382737 | Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment.<br>***Note: Radiation therapy is addressed in Questions 53-54. Pharmaceutical therapy is addressed in Questions 46-52.*** |
| 46 | Neoadjuvant chemotherapy type | ☐ Cytotoxic chemotherapy<br>☐ Hormonal<br>☐ Immunotherapy (cellular and immune checkpoint)<br>☐ Targeted therapy (small molecule inhibitors and targeted antibodies)<br>☐ Not applicable | 5832928 | Select all neoadjuvant chemotherapy types that were administered to the patient.<br>***Note: Cytotoxic chemotherapy is addressed in Questions 47-48. Immunotherapy is addressed in Questions 49-50. Targeted therapy is addressed in Questions 51-52.*** |


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| 47 | Neoadjuvant chemotherapeutic regimen | ☐ Cisplatin<br>☐ Docetaxel<br>☐ Doxorubicin<br>☐ Etoposide<br>☐ Ifosfamide<br>☐ Methotrexate<br>☐ Vincristine<br>☐ Vincristine, actinomycin-D, cyclophosphamide (VAC)<br>☐ Vincristine, doxorubicin, cyclophosphamide, ifosfamide, etoposide (VDC/IE)<br>☐ Vincristine, actinomycin-D, cyclophosphamide, vincristine, irinotecan (VAC/VI)<br>☐ Ifosfamide, carboplatin, etoposide (ICE)<br>☐ Vincristine, irinotecan, temozolomide (VIT)<br>☐ High-dose methotrexate, doxorubicin, cisplatin (MAP)<br>☐ Other (specify)<br>☐ Chemotherapy not given | 2853313 | Select all chemotherapeutics used for neoadjuvant therapy.<br>***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.*** |
| 47a | Other neoadjuvant chemotherapeutic regimen | _____ | 62694 | If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapy. |
| 48 | 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. |
| 49 | Immunotherapy name, specify | _____ | 2185614 | Specify the name of the immunotherapy administered.<br>***Note: If immunotherapy was not given, skip to Question 51.*** |
| 50 | Days to immunotherapy treatment from index date | _____ | 5102411 | Provide the number of days from the index date to the date of treatment with immunotherapy. |
| 51 | Targeted molecular therapy name, specify | _____ | 2842797 | Specify the targeted therapy administered to the patient.<br>***Note: If targeted therapy was not given, skip to Question 53.*** |
| 52 | 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. |
| 53 | Radiation therapy administered type | ☐ 2D conventional<br>☐ 3D conformal<br>☐ Brachytherapy HDR<br>☐ Brachytherapy LDR<br>☐ IMRT<br>☐ Proton Beam<br>☐ Stereotactic Body RT<br>☐ Stereotactic Radiosurgery<br>☐ WBRT<br>☐ Other (specify)<br>☐ Unspecified<br>☐ Not applicable | 3028890 | Provide the type of radiation therapy that was administered to the patient.<br>***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.*** |


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| 53a | Other radiation therapy | _____ | 2195477 | If the radiation therapy type is not included in the provided list, specify the type. |
| 54 | 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. |