Enrollment: Esophageal

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	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.
5	Height	_____	649	Provide the patient's height, in centimeters.
6	Weight	_____	651	Provide the patient's weight, in kilograms.
7	Body mass index (BMI)	_____	2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
8	Race	☐ 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.
9	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
10	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.
11	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. *Note: If the patient's age is greater than 32,872 days (90 years), please enter 32,872.*
12	Year of birth	_____	2896954	Provide the year of the patient's birth. If the patient was born prior to 1928, insert the date 1928.
13	Family history of cancer	☐ 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 ☐ Brain ☐ Liver ☐ Lung ☐ Other (specify)	3108271	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(s)	_____	3128033	If the site of metastasis is not included on the provided list, specify the site of metastasis.
Biospecimen Information				
17	Tissue sample type(s) collected for HCMI for this case	☐ 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.*

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
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.*
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: The first biospecimen should be number "1," the second should be number "2," etc.*
24	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
25	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
26	Type of normal control	☐ 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	☐ Esophagus – proximal third ☐ Esophagus – middle third ☐ Esophagus – distal third ☐ 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.*

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
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 ☐ OCT ☐ FFPE ☐ Snap frozen ☐ 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	☐ C15.0 ☐ C15.5 ☐ C15.1 ☐ C15.8 ☐ C15.2 ☐ C15.9 ☐ C15.3 ☐ Other (specify) ☐ C15.4	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.*
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	☐ 8020/3 ☐ 8140/3 ☐ 8051/3 ☐ 8200/3 ☐ 8070/3 ☐ 8430/3 ☐ 8074/3 ☐ 8560/3 ☐ 8083/3 ☐ 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	Specify other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.
32	Tissue or organ of origin	☐ Esophagus ☐ Other (specify)	3427536	Using the patient's pathology/laboratory report, select the primary site of the disease. *Note: If the primary site of the disease is not listed, proceed to Question 32a, otherwise skip to Question 33.*
32a	Other tissue or organ of origin	_____	5946219	If the primary site of the disease is not included on the previous list, provide the primary site of the disease.
33	Histological Type	☐ Esophageal cancer ☐ Other (specify)	3081932	Select the surgical pathology text description of the histological tumor type. *Note: If the histological tumor type is not listed, proceed to Question 33a, otherwise, skip to Question 34.*
33a	Other histological type	_____	3294805	If the traditional surgical pathology text description of the histological tumor type is not included on the previous list, please specify the histological type.
34	Histological subtype	☐ Esophagus adenocarcinoma (NOS) ☐ Esophagus squamous cell carcinoma ☐ Other (specify)	3081934	Using the patient's pathology/laboratory report, select the histological subtype of the primary tumor. *Note: If the histological subtype is not listed, proceed to Question 34a, otherwise, skip to Question 35.*
34a	Other histological subtype	_____	3124492	If the histological subtype for the primary tumor is not included in the provided list, specify the histological subtype.

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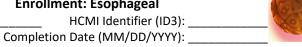| Question	Question Text	Data Entry Options	CDE ID	Instruction Text
35	Prior malignancy (of the same cancer type)	☐ Yes ☐ No ☐ Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
36	Prior malignancy (other cancer type)	☐ Yes ☐ No ☐ Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.
37	AJCC cancer staging edition	☐ 1st ☐ 5th ☐ 2nd ☐ 6th ☐ 3rd ☐ 7th ☐ 4th ☐ 8th	2722309	Select the AJCC staging handbook edition used to stage the patient's primary tumor.
38	Clinical stage group	☐ Stage 0 ☐ Stage III ☐ Stage I ☐ Stage IIIA ☐ Stage IA ☐ Stage IIIB ☐ Stage IB ☐ Stage IIIC ☐ Stage II ☐ Stage IV ☐ Stage IIA ☐ Stage IVA ☐ Stage IIB ☐ Stage IVB	3440332	Using the patient's pathology/laboratory report, select the clinical stage group of the primary tumor as defined by the American Joint Committee on Cancer (AJCC).
39	AJCC pathologic spread: Primary tumor (pT)	☐ T0 ☐ T1b ☐ T4a ☐ Tis ☐ T2 ☐ T4b ☐ T1 ☐ T3 ☐ TX ☐ T1a ☐ T4	3045435	Using the patient's pathology/laboratory report, select the code for the pathologic T (primary tumor) as defined by the American Joint Committee on Cancer (AJCC).
40	AJCC pathologic spread: Lymph nodes (pN)	☐ N0 ☐ N3 ☐ N1 ☐ NX ☐ N2	3203106	Using the patient's pathology/laboratory report, select the code for the pathologic N (nodal) as defined by the American Joint Committee on Cancer (AJCC).
41	AJCC pathologic spread: Distant metastases (pM)	☐ M0 ☐ M1	3045439	Using the patient's pathology/laboratory report, select the code for the pathologic M (metastasis) as defined by the American Joint Committee on Cancer (AJCC).
42	Tumor stage (pathological)	☐ Stage 0 ☐ Stage IIIA ☐ Stage IA ☐ Stage IIIB ☐ Stage IB ☐ Stage IIIC ☐ Stage IC ☐ Stage IV ☐ Stage IIA ☐ Stage IVA ☐ Stage IIB ☐ Stage IVB	3065862	Using the patient's pathology/laboratory report, in conjunction with the patient's medical record, select the stage as defined by the American Joint Committee on Cancer (AJCC).
43	Tumor grade	☐ G1-Well differentiated ☐ G2-Moderately differentiated ☐ G3-Poorly differentiated ☐ GX-Unknown	2785839	Using the patient's pathology/laboratory report, select the grade of the primary tumor.
Prognostic/Predictive/Lifestyle Features for Primary Tumor Prognosis or Responsiveness to Treatment				
44	Does the tumor cross the gastric/esophageal junction (GEJ)?	☐ Yes ☐ No ☐ Unknown	3295807	Indicate whether the tumor is located across the gastroesophageal junction.
45	Alcohol exposure intensity	☐ Lifelong non-drinker ☐ Non-drinker ☐ Occasional drinker ☐ Drinker ☐ Heavy drinker ☐ Not evaluated	3457767	Describe the patient's current level of alcohol use as self-reported by the patient.
46	Frequency of alcohol consumption (days per week)	_____	3114013	Describe the average number of days each week that the patient consumes an alcoholic beverage.

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
47	Did the patient have a prior clinical diagnosis of reflux disease?	☐ Yes ☐ No ☐ Unknown	3203079	Indicate whether the patient has a history of reflux disease. ***Note: If the patient was not diagnosed with reflux disease, skip to Question 49.***
48	How was the patient treated for reflux disease?	☐ Antacids ☐ H2 blockers ☐ Medically treated ☐ Proton pump inhibitors ☐ Surgically treated ☐ No treatment ☐ Unknown	3440206	If the patient was clinically diagnosed with reflux disease, select all methods by which the patient was treated.
49	Previous or current H. pylori infection?	☐ Previous ☐ Current ☐ Never ☐ Unknown	3440211	Indicate whether the patient was previously or is currently diagnosed with Helicobacter pylori infection.
50	Previous or current diagnosis of Barrett's Esophagus?	☐ Yes ☐ No ☐ Unknown	3203140	Indicate whether the patient had a previous or has a current diagnosis of Barrett's esophagus. ***Note: If the patient was not diagnosed with Barrett's Esophagus, skip to Question 52.***
51	Were goblet cells present?	☐ Yes ☐ No ☐ Unknown	3440216	If the patient was clinically diagnosed with Barrett's Esophagus, indicate whether there were goblet cells present.
52	Esophageal columnar metaplasia present?	☐ Yes ☐ No ☐ Unknown	3440218	Indicate whether the patient had esophageal columnar metaplasia present.
53	Goblet cells of esophageal columnar mucosa present (i.e. possible specialized Barrett's esophagus mucosa)?	☐ Yes ☐ No ☐ Unknown	3440219	Indicate whether goblet cells were present in esophageal columnar mucosa.
54	Degree of dysplasia within the non-cancerous esophageal columnar mucosa	☐ Negative/no dysplasia ☐ Low grade dysplasia ☐ High grade dysplasia ☐ Indefinite for dysplasia ☐ Unknown	3440917	Provide the patient's degree of dysplasia within the non-cancerous esophageal columnar mucosa.
55	Number of pack years smoked	_____	2955385	Provide the number of pack years the patient smoked. ***Note: This is calculated using the number of cigarettes smoked per day times the number of years smoked, divided by 20. For example, if a patient smoked 5 cigarettes per day times 10 years, divided by 20, the patient would have 2.5 pack years (e.g. 5 x 10 / 20 = 2.5).***
56	Tobacco smoking quit year	_____	2228610	Provide the year the patient quit smoking. ***Note: If the patient has not quit smoking, never smoked, or the year is unknown, leave the response section blank.***
Primary Tumor Sample Information				
57	Are you submitting a primary tumor tissue sample for this case?	☐ Yes ☐ No		***If yes, proceed to question 58.*** ***If submitting a metastatic/recurrent tumor sample, proceed to Question 84.***
58	Primary tumor biospecimen ordinal	_____	6584265	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number should be "1".***

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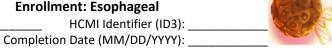| Question	Question Text	Data Entry Options	CDE ID	Instruction Text
59	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
60	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
61	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 62, otherwise, skip to Question 63.*
62	Specify the ICD-10 code	_____	3226287	Provide the ICD-10 code for the primary tumor used to generate the model submitted to HCMI.
63	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.
64	Anatomic Site of tumor from which Model was Derived	☐ Esophagus – proximal third ☐ Esophagus – middle third ☐ Esophagus – distal third ☐ Gastroesophageal junction ☐ Bone ☐ Brain ☐ Liver ☐ Lung ☐ Lymph node ☐ Other (specify)	4214629	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI. *Note: If the tissue or organ of origin is not listed, proceed to Question 64a. Otherwise, skip to Question 65.*
64a	Other anatomic site from which the tumor was obtained	_____	5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.
65	Method of cancer sample procurement	☐ Endoscopic biopsy ☐ Endoscopic mucosal resection ☐ Surgical resection ☐ Laparoscopic biopsy ☐ Other (specify)	3103514	Provide the procedure performed to obtain the primary tumor tissue. *Note: If the method of procurement is not listed, proceed to Question 65a, otherwise, skip to Question 66.*
65a	Specify the other method of tumor sample procurement	_____	2006730	Specify the procedure performed to obtain the primary tumor tissue, if not included in the previous list.
66	Number of days from index date to date of tumor sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the tumor tissue submitted for HCMI.
67	Tumor tissue type	☐ Primary ☐ Additional Primary ☐ NOS	3288124	Provide the primary tumor tissue type for this sample.
Primary Tumor Model Information				
68	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".*
69	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.

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
70	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.
71	Model represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this MODEL represent the PRIMARY DIAGNOSIS for this Case ID3?
72	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.
73	Model's primary tumor biospecimen ordinal	_____	6584265	Enter the biospecimen ordinal of the PRIMARY TUMOR TISSUE from which this model is derived.
Treatment Information				
74	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 75-81. Radiation therapy is addressed in Questions 82-83.*
75	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 76-77. Immunotherapy is addressed in Questions 78-79. Targeted therapy is addressed in Questions 80-81.*
76	Neoadjuvant chemotherapeutic regimen	☐ Cisplatin; 5-fluorouracil (CF) ☐ Cisplatin; Capecitabine (CX) ☐ Epirubicin; Cisplatin; 5-fluorouracil (ECF) ☐ Epirubicin; Cisplatin; Capecitabine (ECX) ☐ Epirubicin; Oxaliplatin; Capecitabine (EOX) ☐ Other (specify) ☐ Chemotherapy not given	2853313	Select all chemotherapeutics used for neoadjuvant therapy. *Note: If neoadjuvant chemotherapy was not given, skip to Question 78. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 76a, otherwise, skip to Question 77.*
76a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapies administered.
77	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.
78	Immunotherapy	_____	2185614	Specify the name of the immunotherapy administered. *Note: If immunotherapy was not given, skip to Question 80, otherwise proceed to Question 79.*
79	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
80	Targeted Therapy	☐ Ramucirumab ☐ Trastuzumab ☐ Other (specify)	5880217	Select the targeted therapy administered to the patient. *Note: If the targeted therapy regimen is not listed, proceed to Question 80a, otherwise, skip to Question 81.*
80a	Specify targeted therapy	_____	4308476	Provide the name of the targeted therapy administered to the patient.

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
81	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.
82	Radiation therapy administered type	☐ 2D conventional ☐ Stereotactic Body RT ☐ 3D conformal ☐ Stereotactic Radiosurgery ☐ Brachytherapy HDR ☐ Brachytherapy LDR ☐ WBRT ☐ IMRT ☐ Other (specify) ☐ Proton Beam ☐ Unspecified ☐ Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. *Note: If radiation therapy was not administered, proceed to Question 84. If the radiation therapy is not listed, proceed to Question 82a, otherwise, skip to Question 83.*
82a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
83	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

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
84	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 85. If submitting an OTHER tissue sample, proceed to Question 136.*
85	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.*
86	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.
87	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.
88	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.
89	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.
90	Method of metastatic/ recurrent cancer sample procurement	☐ Endoscopic biopsy ☐ Endoscopic mucosal resection ☐ Surgical resection ☐ Laparoscopic biopsy ☐ Other (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 90a, otherwise, skip to Question 91.*
90a	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.
91	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
92	Metastatic/recurrent site	☐ Esophagus - proximal third ☐ Esophagus - middle third ☐ Esophagus - distal third ☐ Gastroesophageal junction ☐ Bone ☐ Brain ☐ Liver ☐ Lung ☐ Lymph node ☐ 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 92a, otherwise, skip to Question 93.*
92a	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.
93	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
94	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
95	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.
96	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.
97	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.
98	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.
99	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
100	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
Prognostic/Predictive/Lifestyle Features for Metastatic/Recurrent Tumor Prognosis or Responsiveness to Treatment				
101	Does the tumor cross the gastric/esophageal junction (GEJ)?	☐ Yes ☐ No ☐ Unknown	3295807	Indicate whether the tumor is located across the gastroesophageal junction.
102	Esophageal columnar metaplasia present?	☐ Yes ☐ No ☐ Unknown	3440218	Indicate whether the patient had esophageal columnar metaplasia present.

Enrollment: Esophageal

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
103	Goblet cells of esophageal columnar mucosa present (i.e. possible specialized Barrett's esophagus mucosa)?	☐ Yes ☐ No ☐ Unknown	3440219	Indicate whether goblet cells were present in esophageal columnar mucosa.
104	Degree of dysplasia within the non-cancerous esophageal columnar mucosa	☐ Negative/no dysplasia ☐ Low grade dysplasia ☐ High grade dysplasia ☐ Indefinite for dysplasia ☐ Unknown	3440917	Provide the patient's degree of dysplasia within the non-cancerous esophageal columnar mucosa.
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 126.***
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 additional metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of additional metastatic/recurrent disease.
111	Method of metastatic/ recurrent cancer sample procurement	☐ Endoscopic biopsy ☐ Endoscopic mucosal resection ☐ Surgical resection ☐ Laparoscopic biopsy ☐ Other (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.

Enrollment: Esophageal

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
113	Metastatic/ recurrent site	☐ Esophagus - proximal third ☐ Esophagus - middle third ☐ Esophagus - distal third ☐ Gastroesophageal junction ☐ Bone ☐ Brain ☐ Liver ☐ Lung ☐ Lymph node ☐ 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 ☐ Distant ☐ Regional ☐ 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 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.
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.
Prognostic/Predictive/Lifestyle Features for Additional Metastatic/Recurrent Tumor Prognosis or Responsiveness to Treatment				
122	Does the tumor cross the gastric/esophageal junction (GEJ)?	☐ Yes ☐ No ☐ Unknown	3295807	Indicate whether the tumor is located across the gastroesophageal junction.
123	Esophageal columnar metaplasia present?	☐ Yes ☐ No ☐ Unknown	3440218	Indicate whether the patient had esophageal columnar metaplasia present.
124	Goblet cells of esophageal columnar mucosa present (i.e. possible specialized Barrett's esophagus mucosa)?	☐ Yes ☐ No ☐ Unknown	3440219	Indicate whether goblet cells were present in esophageal columnar mucosa.

Enrollment: Esophageal

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
125	Degree of dysplasia within the non-cancerous esophageal columnar mucosa	☐ Negative/no dysplasia ☐ Low grade dysplasia ☐ High grade dysplasia ☐ Indefinite for dysplasia ☐ Unknown	3440917	Provide the patient's degree of dysplasia within the non-cancerous esophageal columnar mucosa.
Metastatic/Recurrent Tumor Model Information				
126	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.*
127	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.
128	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.
129	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.
130	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)				
131	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.*
132	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.
133	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.
134	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.
135	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				
136	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 137.*
137	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.*

Enrollment: Esophageal

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
138	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.
139	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.
140	OTHER tissue sample preservation method	☐ Cryopreserved ☐ OCT ☐ FFPE ☐ Snap frozen ☐ Frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
141	Other method of cancer sample procurement	☐ Endoscopic biopsy ☐ Endoscopic mucosal resection ☐ Surgical resection ☐ Laparoscopic biopsy ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. *Note: If the method of procurement is not listed, proceed to Question 141a, otherwise, skip to Question 142.*
141a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
142	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.
143	Tissue type	☐ Non-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. *Note: If the OTHER tissue type is not listed, proceed to Question 143a, otherwise, skip to Question 144.*
143a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
144	Anatomic site of OTHER tissue	☐ Esophagus - proximal third ☐ Esophagus - middle third ☐ Brain ☐ Esophagus - distal third ☐ Liver ☐ Lung ☐ Gastroesophageal junction ☐ Lymph node ☐ Other (specify) ☐ Bone	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 144a, otherwise, skip to Question 145.*
144a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.
145	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
146	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.
Additional OTHER biospecimen Information (if applicable)				
147	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 148, otherwise, skip to Question 158.*
148	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.*

Enrollment: Esophageal

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
149	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.
150	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.
151	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.
152	Other method of cancer sample procurement	☐ Endoscopic biopsy ☐ Endoscopic mucosal resection ☐ Surgical resection ☐ Laparoscopic biopsy ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. *Note: If the method of procurement is not listed, proceed to Question 152a, otherwise, skip to Question 153.*
152a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
153	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.
154	Tissue type	☐ Non-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. *Note: If the OTHER tissue type is not listed, proceed to Question 154a, otherwise, skip to Question 155.*
154a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
155	Anatomic site of OTHER tissue	☐ Esophagus - proximal third ☐ Esophagus - middle third ☐ Esophagus - distal third ☐ Gastroesophageal junction ☐ Bone ☐ Brain ☐ Liver ☐ Lung ☐ Lymph node ☐ 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 155a, otherwise, skip to Question 156.*
155a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.
156	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
157	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				
158	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.*

Enrollment: Esophageal

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
159	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.
160	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.
161	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
162	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)				
163	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.*
164	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.
165	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
166	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
167	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.