

## Enrollment: Ampulla of Vater

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	<input type="checkbox"/> Initial pathologic diagnosis <input type="checkbox"/> Sample procurement <input type="checkbox"/> 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.
<b>Patient Information</b>				
4	Gender	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> 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	<input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian or other Pacific Islander <input type="checkbox"/> White <input type="checkbox"/> Unknown <input type="checkbox"/> Not reported	2192199	Provide the patient's race using the defined categories. <b>American Indian or Alaska Native:</b> 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. <b>Asian:</b> 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. <b>Black or African American:</b> A person having origins in any of the black racial groups of Africa. <b>Native Hawaiian or other Pacific Islander:</b> A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island. <b>White:</b> A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
9	Ethnicity	<input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Unknown <input type="checkbox"/> Not reported	2192217	Provide the patient's ethnicity using the defined categories. <b>Hispanic or Latino:</b> A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. <b>Not Hispanic or Latino:</b> 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. <b>Note: If the patient's age is greater than 32,872 days (90 years), please enter 32,872.</b>
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	<input type="checkbox"/> Same <input type="checkbox"/> Different <input type="checkbox"/> None <input type="checkbox"/> 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	<input type="checkbox"/> Lifelong non-smoker (<100 cigarettes smoked in a lifetime) <input type="checkbox"/> Current smoker (includes daily and non-daily smokers) <input type="checkbox"/> Current reformed smoker (duration not specified) <input type="checkbox"/> Current reformed smoker for >15 years <input type="checkbox"/> 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	<input type="checkbox"/> Metastatic <input type="checkbox"/> Non-metastatic (confirmed) <input type="checkbox"/> Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor. <b>Note: If metastatic at diagnosis, proceed to Question 16, otherwise, skip to Question 17.</b>
16	Metastatic site(s) at diagnosis	<input type="checkbox"/> Bone <input type="checkbox"/> Brain <input type="checkbox"/> Kidney <input type="checkbox"/> Liver <input type="checkbox"/> Lung <input type="checkbox"/> Lymph node(s) distant <input type="checkbox"/> Lymph node(s) regional <input type="checkbox"/> Peritoneum <input type="checkbox"/> Other (specify)	3029815	Indicate the site(s) of metastasis at the time of diagnosis of the primary tumor. <b>Note: If the anatomic site of tumor tissue is not listed, proceed to Question 16a, otherwise, skip to Question 17.</b>
16a	Specify metastatic site(s)	_____	3128033	If the site of metastasis is not included on the provided list, specify the site of metastasis.
<b>Biospecimen Information</b>				
17	Tissue sample type(s) collected for HCMI for this case	<input type="checkbox"/> Normal tissue <input type="checkbox"/> Primary tumor <input type="checkbox"/> Metastatic <input type="checkbox"/> Recurrent <input type="checkbox"/> 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. <b>Note: This number is expected to be 1.</b>
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. <b>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.</b>

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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. <b>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.</b>
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. <b>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.</b>
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. <b>Note: This number should be the sum of the normal, primary tumor, metastatic/recurrent tumor, and other biospecimen counts above.</b>
<b>Normal Control Information</b>				
23	Normal tissue biospecimen ordinal	_____	6584264	Please provide a number to identify which biospecimen this is in the sequence. <b>Note: The first biospecimen should be number "1," the second should be number "2," etc.</b>
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	<input type="checkbox"/> Whole blood <input type="checkbox"/> Buccal cells <input type="checkbox"/> Buffy coat <input type="checkbox"/> Lymphocytes <input type="checkbox"/> Extracted DNA from blood <input type="checkbox"/> Extracted DNA from saliva <input type="checkbox"/> Extracted DNA from buccal cells <input type="checkbox"/> Extracted DNA from normal tissue <input type="checkbox"/> FFPE non-neoplastic tissue <input type="checkbox"/> Non-neoplastic tissue	3081936	Indicate the type of normal control submitted for this case.
27	Anatomic site of normal tissue	<input type="checkbox"/> Duodenum <input type="checkbox"/> Periapillary pancreas <input type="checkbox"/> Other (specify) <input type="checkbox"/> Not applicable	4132152	If non-neoplastic tissue was submitted as the normal control, select the anatomic site of the normal tissue. <b>Note: If the anatomic site of normal tissue is not listed, proceed to Question 27a, otherwise, skip to Question 28.</b>

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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)	<input type="checkbox"/> Adjacent (< or = 2cm) <input type="checkbox"/> Distal (>2cm) <input type="checkbox"/> Unknown <input type="checkbox"/> Not applicable	3088708	Indicate the distance from the site of normal tumor collection to the primary tumor. <b>Note: If normal tissue was not submitted, select 'Not applicable'.</b>
29	Normal tissue sample preservation method	<input type="checkbox"/> Cryopreserved <input type="checkbox"/> OCT <input type="checkbox"/> FFPE <input type="checkbox"/> Snap frozen <input type="checkbox"/> Frozen	5432521	Provide the method used to preserve the normal tissue sample collected for molecular characterization.
<b>Primary Tumor Biospecimen Information</b>				
30	ICD-10 code for primary tumor	<input type="checkbox"/> C24.1 <input type="checkbox"/> Other (specify)	3226287	Provide the ICD-10 code for the primary tumor as used to generate the ID3 for this subject. <b>Note: If the ICD-10 code is not listed, proceed to 30a, otherwise, skip to Question 31.</b>
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	<input type="checkbox"/> 8013/3 <input type="checkbox"/> 8156/3 <input type="checkbox"/> 8310/3 <input type="checkbox"/> 8020/3 <input type="checkbox"/> 8240/3 <input type="checkbox"/> 8480/3 <input type="checkbox"/> 8035/3 <input type="checkbox"/> 8241/3 <input type="checkbox"/> 8490/3 <input type="checkbox"/> 8041/3 <input type="checkbox"/> 8244/3 <input type="checkbox"/> 8560/3 <input type="checkbox"/> 8070/3 <input type="checkbox"/> 8246/3 <input type="checkbox"/> 8576/3 <input type="checkbox"/> 8140/3 <input type="checkbox"/> 8249/3 <input type="checkbox"/> Other <input type="checkbox"/> 8144/3 <input type="checkbox"/> 8260/3    (specify)	3226275	Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor. <b>Note: If the ICD-O-3 histology code of the primary tumor is not listed, proceed to Question 31a, otherwise, skip to Question 32.</b>
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	<input type="checkbox"/> Ampulla of Vater <input type="checkbox"/> Other (specify)	3427536	Using the patient's pathology/laboratory report, select the primary site of the disease. <b>Note: If the primary site of the disease is not listed, proceed to Question 32a, otherwise skip to Question 33.</b>
32a	Other tissue or organ of origin	<input type="checkbox"/> Abdomen <input type="checkbox"/> Other ill-defined sites <input type="checkbox"/> Accessory sinus <input type="checkbox"/> Ovary <input type="checkbox"/> Adrenal gland <input type="checkbox"/> Palate <input type="checkbox"/> Anus <input type="checkbox"/> Pancreas <input type="checkbox"/> Appendix <input type="checkbox"/> Penis <input type="checkbox"/> Bladder <input type="checkbox"/> Peripheral nerves and autonomic nervous system of trunk <input type="checkbox"/> Bone <input type="checkbox"/> Peritoneum <input type="checkbox"/> Breast <input type="checkbox"/> Pharynx <input type="checkbox"/> Connective, subcutaneous and other soft tissues <input type="checkbox"/> Pituitary gland <input type="checkbox"/> Esophagus <input type="checkbox"/> Prostate gland <input type="checkbox"/> Eye <input type="checkbox"/> Rectosigmoid junction <input type="checkbox"/> Gallbladder <input type="checkbox"/> Renal pelvis <input type="checkbox"/> Gum <input type="checkbox"/> Retroperitoneum <input type="checkbox"/> Head, face or neck <input type="checkbox"/> Skin <input type="checkbox"/> Heart <input type="checkbox"/> Small intestine <input type="checkbox"/> Kidney <input type="checkbox"/> Spinal cord	3427536	If the primary site of the disease is not included on the previous list, provide the primary site of the disease.

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		<input type="checkbox"/> Larynx <input type="checkbox"/> Lip <input type="checkbox"/> Liver <input type="checkbox"/> Lung <input type="checkbox"/> Lymph node <input type="checkbox"/> Male genital organs <input type="checkbox"/> Mediastinum <input type="checkbox"/> Meninges <input type="checkbox"/> Mouth <input type="checkbox"/> Nasal cavity <input type="checkbox"/> Nasopharynx <input type="checkbox"/> Nervous system <input type="checkbox"/> Oropharynx	<input type="checkbox"/> Spleen <input type="checkbox"/> Stomach <input type="checkbox"/> Testis <input type="checkbox"/> Thymus <input type="checkbox"/> Thyroid gland <input type="checkbox"/> Tongue <input type="checkbox"/> Tonsil <input type="checkbox"/> Trachea <input type="checkbox"/> Unknown primary <input type="checkbox"/> Urinary system <input type="checkbox"/> Uterus <input type="checkbox"/> Vagina <input type="checkbox"/> Vulva		
33	Histological Type	<input type="checkbox"/> Cancer of the Ampulla of Vater <input type="checkbox"/> Other (specify) _____		3081932	Select the surgical pathology text description of the histological tumor type. <b>Note: If the histological tumor type is not listed, proceed to Question 33a, otherwise, skip to Question 34.</b>
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	<input type="checkbox"/> Adenocarcinoma <input type="checkbox"/> Adenocarcinoma with peculiar aspects <input type="checkbox"/> Hepatoid carcinoma <input type="checkbox"/> Medullary carcinoma <input type="checkbox"/> Mixed adenoneuroendocrine carcinoma <input type="checkbox"/> Moderately-differentiated neuroendocrine carcinoma <input type="checkbox"/> Neuroendocrine carcinoma- large cell <input type="checkbox"/> Neuroendocrine carcinoma- small cell <input type="checkbox"/> Undifferentiated carcinoma <input type="checkbox"/> Well-differentiated neuroendocrine carcinoma <input type="checkbox"/> Other (specify) _____ <input type="checkbox"/> Unknown		3081934	Using the patient's pathology/laboratory report, select the histological subtype of the primary tumor. <b>Note: If the histological subtype is not listed, proceed to Question 34a, otherwise, skip to Question 35.</b>
34a	Other histological subtype	_____		3124492	If the histological subtype for the primary tumor is not included in the provided list, specify the histological subtype.
35	If AVC histological subtype is adenocarcinoma, select the histotype	<input type="checkbox"/> Intestinal <input type="checkbox"/> Mixed <input type="checkbox"/> Pancreatico-biliary <input type="checkbox"/> Unknown		6326080	If the histological subtype for the primary tumor is adenocarcinoma, specify the histotype.
36	If the AVC histological subtype is adenocarcinoma with peculiar aspects, select the subtype	<input type="checkbox"/> Clear cell <input type="checkbox"/> Mucinous <input type="checkbox"/> Signet ring <input type="checkbox"/> Squamous differentiation <input type="checkbox"/> Unknown		6326081	If the histological subtype for the primary tumor is adenocarcinoma with peculiar aspects, specify the subtype.
37	If well- or moderately-differentiated neuroendocrine tumor, specify the hormones released	_____		6326082	If the histological subtype for the primary tumor is well-differentiated or moderately-differentiated neuroendocrine tumor, please specify the hormones released. If the histological subtype is not well-or moderately-differentiated neuroendocrine tumor, please leave this section blank.

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
38	Prior malignancy (of the same cancer type)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
39	Prior malignancy (other cancer type)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.
40	AJCC cancer staging edition	<input type="checkbox"/> 1 <sup>st</sup> <input type="checkbox"/> 4 <sup>th</sup> <input type="checkbox"/> 7 <sup>th</sup> <input type="checkbox"/> 2 <sup>nd</sup> <input type="checkbox"/> 5 <sup>th</sup> <input type="checkbox"/> 8 <sup>th</sup> <input type="checkbox"/> 3 <sup>rd</sup> <input type="checkbox"/> 6 <sup>th</sup>	2722309	Select the AJCC staging handbook edition used to stage the patient's primary tumor.
41	Clinical stage group	<input type="checkbox"/> Stage 0 <input type="checkbox"/> Stage III <input type="checkbox"/> Stage IA <input type="checkbox"/> Stage IIIA <input type="checkbox"/> Stage IB <input type="checkbox"/> Stage IIIB <input type="checkbox"/> Stage IIA <input type="checkbox"/> Stage IV <input type="checkbox"/> Stage IIB	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).
42	AJCC pathologic spread: Primary tumor (pT)	<input type="checkbox"/> T0 <input type="checkbox"/> T1b <input type="checkbox"/> T3b <input type="checkbox"/> Tis <input type="checkbox"/> T2 <input type="checkbox"/> T4 <input type="checkbox"/> T1 <input type="checkbox"/> T3 <input type="checkbox"/> TX <input type="checkbox"/> T1a <input type="checkbox"/> T3a	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).
43	AJCC pathologic spread: Lymph nodes (pN)	<input type="checkbox"/> NX <input type="checkbox"/> N0 <input type="checkbox"/> N1 <input type="checkbox"/> 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).
44	AJCC pathologic spread: Distant metastases (pM)	<input type="checkbox"/> M0 <input type="checkbox"/> 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).
45	Tumor stage (pathological)	<input type="checkbox"/> Stage 0 <input type="checkbox"/> Stage III <input type="checkbox"/> Stage IA <input type="checkbox"/> Stage IIIA <input type="checkbox"/> Stage IB <input type="checkbox"/> Stage IIIB <input type="checkbox"/> Stage IIA <input type="checkbox"/> Stage IV <input type="checkbox"/> Stage IIB	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).
46	Tumor grade	<input type="checkbox"/> G1-Well differentiated <input type="checkbox"/> G2-Moderately differentiated <input type="checkbox"/> G3-Poorly differentiated <input type="checkbox"/> GX-Unknown	2785839	Using the patient's pathology/laboratory report, select the grade of the primary tumor.
47	Tumor extension	<input type="checkbox"/> Carcinoma in situ/high-grade dysplasia <input type="checkbox"/> Tumor limited to ampulla of Vater or sphincter of Oddi <input type="checkbox"/> Tumor invades beyond sphincter of Oddi (perisphincteric invasion) <input type="checkbox"/> Tumor invades into duodenal submucosa <input type="checkbox"/> Tumor invades into muscularis propria of the duodenum <input type="checkbox"/> Tumor directly invades pancreas up to 0.5 cm <input type="checkbox"/> Tumor extends more than 0.5 cm into pancreas <input type="checkbox"/> Tumor extends into peripancreatic soft tissues <input type="checkbox"/> Tumor extends into periduodenal tissue <input type="checkbox"/> Tumor extends into duodenal serosa <input type="checkbox"/> Tumor invades other adjacent organs or structures other than pancreas (specify) <input type="checkbox"/> Cannot be assessed	6326086	Select all options that represent the extent to which the Ampulla of Vater tumor has invaded through the wall of an organ into surrounding organs and/or adjacent tissues.  <b>Note: If the tumor invades into other adjacent organs, proceed to Question 47a, otherwise skip to Question 48.</b>



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
47a	Tumor extension other structures	_____	64351	If the Ampulla of Vater tumor has invaded adjacent organs or structures other than the pancreas, please specify the organ(s).
48	Venous invasion present?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	64358	Indicate whether venous invasion was present in the tumor specimen. <b>Note: If venous invasion was identified in the tumor specimen, proceed to Question 49, otherwise skip to Question 50.</b>
49	Venous invasion type	<input type="checkbox"/> Extramural <input type="checkbox"/> Intramural <input type="checkbox"/> Unknown	6036344	Identify the location of vascular involvement for the tumor.
50	Lymphatic invasion present?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	64171	Indicate if malignant cells are present in small or thin-walled vessels, suggesting lymphatic involvement.
51	Perineural invasion present?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	64181	Indicate if perineural invasion or infiltration of tumor or cancer is present.
52	Number of positive lymph nodes	_____	89	Provide the number of lymph nodes involved with disease as determined by pathologic examination.
53	Number of lymph nodes examined	_____	3	Provide the number of lymph nodes removed and pathologically assessed for disease.
54	Margins of surgical resection	<input type="checkbox"/> R0 <input type="checkbox"/> RX <input type="checkbox"/> R1 <input type="checkbox"/> Not evaluated <input type="checkbox"/> R2	2608702	Indicate the status of the tissue margins following surgical resection of the tumor submitted for HCMI.
<b>Primary Tumor Sample Information</b>				
55	Are you submitting a primary tumor tissue sample for this case?	<input type="checkbox"/> Yes <input type="checkbox"/> No		<b>If yes, proceed to question 56. If submitting a metastatic/recurrent tumor sample, proceed to Question 84.</b>
56	Primary tumor biospecimen ordinal	_____	6584265	Please provide a number to identify which biospecimen this is in the sequence. <b>Note: This number should be "1".</b>
57	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.
58	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.
59	Sample represents primary diagnosis?	<input type="checkbox"/> Yes <input type="checkbox"/> No	6584730	Does this primary tumor specimen represent the PRIMARY DIAGNOSIS for this Case ID3? <b>Note: If no, continue to Question 60, otherwise, skip to Question 61.</b>
60	Specify the ICD-10 code	_____	3226287	Provide the ICD-10 code for the primary tumor used to generate the model submitted to HCMI.
61	Tumor tissue sample preservation method	<input type="checkbox"/> Cryopreserved <input type="checkbox"/> FFPE <input type="checkbox"/> Frozen <input type="checkbox"/> OCT <input type="checkbox"/> Snap frozen	5432521	Provide the method used to preserve the tumor tissue sample collected for molecular characterization.
62	Anatomic Site of tumor from which Model was Derived	<input type="checkbox"/> Ampulla of Vater <input type="checkbox"/> Bone <input type="checkbox"/> Brain <input type="checkbox"/> Kidney <input type="checkbox"/> Liver <input type="checkbox"/> Lung <input type="checkbox"/> Lymph node <input type="checkbox"/> Peritoneum <input type="checkbox"/> Other (specify)	6033148	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI. <b>Note: If the tissue or organ of origin is not listed, proceed to Question 62a. Otherwise, skip to Question 63.</b>

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
62a	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.
63	Method of cancer sample procurement	<input type="checkbox"/> Ampullectomy <input type="checkbox"/> Pancreaticoduodenectomy <input type="checkbox"/> Other (specify)	3103514	Provide the procedure performed to obtain the primary tumor tissue. <b>Note: If the method of procurement is not listed, proceed to Question 63a, otherwise, skip to Question 64.</b>
63a	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.
64	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.
65	Tumor tissue type	<input type="checkbox"/> Primary <input type="checkbox"/> Additional Primary <input type="checkbox"/> NOS	3288124	Provide the primary tumor tissue type for this sample.
<b>Primary Tumor Model Information</b>				
66	Primary model biospecimen ordinal	_____	6594596	Please provide a number to identify which biospecimen this is in the sequence. <b>Note: This number is expected to be "1".</b>
67	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.
68	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.
69	Model represents primary diagnosis?	<input type="checkbox"/> Yes <input type="checkbox"/> No	6584730	Does this MODEL represent the PRIMARY DIAGNOSIS for this Case ID3?
70	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.
71	Model's primary tumor biospecimen ordinal	_____	6584265	Enter the biospecimen ordinal of the PRIMARY TUMOR TISSUE from which this model is derived.
<b>Treatment Information</b>				
72	History of neoadjuvant treatment	<input type="checkbox"/> No <input type="checkbox"/> Yes; radiation prior to resection <input type="checkbox"/> Yes; pharmaceutical treatment prior to resection <input type="checkbox"/> Yes; both radiation and pharmaceutical treatment prior to resection <input type="checkbox"/> Unknown	3382737	Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment. <b>Note: Pharmaceutical therapy is addressed in Questions 73-81. Radiation therapy is addressed in Questions 82-83.</b>
73	Neoadjuvant chemotherapy type	<input type="checkbox"/> Cytotoxic chemotherapy <input type="checkbox"/> Hormonal <input type="checkbox"/> Immunotherapy (cellular and immune checkpoint) <input type="checkbox"/> Targeted therapy (small molecule inhibitors and targeted antibodies) <input type="checkbox"/> Not applicable	5832928	Select all neoadjuvant chemotherapy types that were administered to the patient. <b>Note: Cytotoxic chemotherapy is addressed in Questions 74-75. Immunotherapy is addressed in Questions 78-79. Targeted therapy is addressed in Questions 80-81.</b>
74	Neoadjuvant chemotherapeutic regimen	<input type="checkbox"/> 5-fluorouracil <input type="checkbox"/> Capecitabine <input type="checkbox"/> Cisplatin <input type="checkbox"/> Gemcitabine <input type="checkbox"/> Oxaliplatin <input type="checkbox"/> Topotecan <input type="checkbox"/> Other (specify) <input type="checkbox"/> Chemotherapy not given	2853313	Select all chemotherapeutics used for neoadjuvant therapy. <b>Note: If neoadjuvant chemotherapy was not given, skip to Question 76. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 74a, otherwise, skip to Question 75.</b>



## Enrollment: Ampulla of Vater

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
74a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapies administered.
75	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.
76	Hormone therapy	<input type="checkbox"/> Lanreotide <input type="checkbox"/> Octreotide <input type="checkbox"/> Other (specify)	6326083	Select the hormone therapy administered to the patient. <b>Note: If the hormone therapy regimen is not listed, proceed to Question 76a, otherwise, skip to Question 77.</b>
76a	Other hormone therapy	_____	2405358	If the hormone therapy is not included in the provided list, specify hormone therapy administered.
77	Days to hormone therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with hormone therapy.
78	Immunotherapy	<input type="checkbox"/> Atezolizumab <input type="checkbox"/> Nivolumab <input type="checkbox"/> Avelumab <input type="checkbox"/> Pembrolizumab <input type="checkbox"/> Durvalumab <input type="checkbox"/> Other (specify)	6326085	Select the immunotherapy administered to the patient. <b>Note: If the immunotherapy regimen is not listed, proceed to Question 78a, otherwise, skip to Question 79.</b>
78a	Other immunotherapy name	_____	2953828	If the immunotherapy is not included in the provided list, specify immunotherapy administered.
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	<input type="checkbox"/> Erlotinib <input type="checkbox"/> Everolimus <input type="checkbox"/> Other (specify)	6326084	Select the targeted therapy administered to the patient. <b>Note: If the targeted therapy regimen is not listed, proceed to Question 80a, otherwise, skip to Question 81.</b>
80a	Specify targeted therapy	_____	4308476	Provide the name of the targeted therapy administered to the patient.
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	<input type="checkbox"/> 2D conventional <input type="checkbox"/> Stereotactic Body RT <input type="checkbox"/> 3D conformal <input type="checkbox"/> Stereotactic Radiosurgery <input type="checkbox"/> Brachytherapy HDR <input type="checkbox"/> WBRT <input type="checkbox"/> Brachytherapy LDR <input type="checkbox"/> Other (specify) <input type="checkbox"/> IMRT <input type="checkbox"/> Unspecified <input type="checkbox"/> Proton Beam <input type="checkbox"/> Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. <b>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.</b>
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.
<b>Metastatic/Recurrent Tumor Biospecimen Information</b>				
84	Are you submitting a metastatic/recurrent tumor tissue sample?	<input type="checkbox"/> Yes <input type="checkbox"/> No		Indicate whether a metastatic/recurrent tumor biospecimen was collected for this ID3 case. <b>Note: If yes, proceed to Question 85. If submitting an OTHER tissue sample, proceed to Question 145.</b>
85	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. <b>Note: The first biospecimen should be number "1", the second should be number "2", etc.</b>

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
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	<input type="checkbox"/> Cryopreserved <input type="checkbox"/> OCT <input type="checkbox"/> FFPE <input type="checkbox"/> Snap frozen <input type="checkbox"/> 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	<input type="checkbox"/> Ampullectomy <input type="checkbox"/> Pancreaticoduodenectomy <input type="checkbox"/> Other (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. <b>Note: If the method of procurement is not listed, proceed to Question 91a, otherwise, skip to Question 92.</b>
91a	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.
92	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.
93	Metastatic/recurrent site	<input type="checkbox"/> Ampulla of Vater <input type="checkbox"/> Lung <input type="checkbox"/> Bone <input type="checkbox"/> Lymph node(s) distant <input type="checkbox"/> Brain <input type="checkbox"/> Lymph node(s) regional <input type="checkbox"/> Kidney <input type="checkbox"/> Peritoneum <input type="checkbox"/> Liver <input type="checkbox"/> Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. <b>Note: If the metastatic/recurrent site is not listed, proceed to Question 93a, otherwise, skip to Question 94.</b>
93a	Other metastatic/ recurrent site	<input type="checkbox"/> Abdomen <input type="checkbox"/> Other ill-defined sites <input type="checkbox"/> Accessory sinus <input type="checkbox"/> Ovary <input type="checkbox"/> Adrenal gland <input type="checkbox"/> Palate <input type="checkbox"/> Anus <input type="checkbox"/> Pancreas <input type="checkbox"/> Appendix <input type="checkbox"/> Penis <input type="checkbox"/> Bladder <input type="checkbox"/> Peripheral nerves and autonomic nervous system of trunk <input type="checkbox"/> Bone <input type="checkbox"/> Peritoneum <input type="checkbox"/> Breast <input type="checkbox"/> Pharynx <input type="checkbox"/> Connective, subcutaneous and other soft tissues <input type="checkbox"/> Pituitary gland <input type="checkbox"/> Esophagus <input type="checkbox"/> Prostate gland <input type="checkbox"/> Eye <input type="checkbox"/> Rectosigmoid junction <input type="checkbox"/> Gallbladder <input type="checkbox"/> Renal pelvis <input type="checkbox"/> Gum <input type="checkbox"/> Retroperitoneum <input type="checkbox"/> Head, face or neck <input type="checkbox"/> Skin <input type="checkbox"/> Heart <input type="checkbox"/> Small intestine <input type="checkbox"/> Kidney <input type="checkbox"/> Spinal cord <input type="checkbox"/> Larynx <input type="checkbox"/> Spleen <input type="checkbox"/> Lip <input type="checkbox"/> Stomach <input type="checkbox"/> Liver <input type="checkbox"/> Testis <input type="checkbox"/> Lung <input type="checkbox"/> Thymus <input type="checkbox"/> Lymph node <input type="checkbox"/> Thyroid gland	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.

## Enrollment: Ampulla of Vater

Tissue Source Site (TSS) Name: \_\_\_\_\_ HCMI Identifier (ID3): \_\_\_\_\_  
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		<input type="checkbox"/> Male genital organs <input type="checkbox"/> Mediastinum <input type="checkbox"/> Meninges <input type="checkbox"/> Mouth <input type="checkbox"/> Nasal cavity <input type="checkbox"/> Nasopharynx <input type="checkbox"/> Nervous system <input type="checkbox"/> Oropharynx	<input type="checkbox"/> Tongue <input type="checkbox"/> Tonsil <input type="checkbox"/> Trachea <input type="checkbox"/> Unknown primary <input type="checkbox"/> Urinary system <input type="checkbox"/> Uterus <input type="checkbox"/> Vagina <input type="checkbox"/> Vulva		
94	Site of relapse	<input type="checkbox"/> Local <input type="checkbox"/> Regional <input type="checkbox"/> Distant <input type="checkbox"/> Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.	
95	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.	
96	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.	
97	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.	
98	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.	
99	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.	
100	Is the patient still receiving treatment?	_____	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.	
101	Disease status	<input type="checkbox"/> No evidence of disease <input type="checkbox"/> Progressive disease <input type="checkbox"/> Stable disease <input type="checkbox"/> Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.	
102	Tumor extension	<input type="checkbox"/> Carcinoma in situ/high-grade dysplasia <input type="checkbox"/> Tumor limited to Ampulla of Vater or sphincter of Oddi <input type="checkbox"/> Tumor invades beyond sphincter of Oddi (perisphincteric invasion) <input type="checkbox"/> Tumor invades into duodenal submucosa <input type="checkbox"/> Tumor invades into muscularis propria of the duodenum <input type="checkbox"/> Tumor directly invades pancreas up to 0.5 cm <input type="checkbox"/> Tumor extends more than 0.5 cm into pancreas <input type="checkbox"/> Tumor extends into peripancreatic soft tissues <input type="checkbox"/> Tumor extends into periduodenal tissue <input type="checkbox"/> Tumor extends into duodenal serosa	6326086	Select all options that represent the extent to which the Ampulla of Vater tumor has invaded through the wall of an organ into surrounding organs and/or adjacent tissues. <b>Note: If the tumor invades into other adjacent organs, proceed to Question 102a, otherwise skip to Question 103.</b>	

## Enrollment: Ampulla of Vater

Tissue Source Site (TSS) Name: \_\_\_\_\_ HCMI Identifier (ID3): \_\_\_\_\_  
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		<input type="checkbox"/> Tumor invades other adjacent organs or structures other than pancreas (specify) <input type="checkbox"/> Cannot be assessed		
102a	Tumor extension other structures	_____	64351	If the Ampulla of Vater tumor has invaded adjacent organs or structures other than the pancreas, please specify the organ(s).
103	Venous invasion present?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	64358	Indicate whether venous invasion was present in the tumor specimen. <b>Note: If venous invasion was identified in the tumor specimen, proceed to Question 104, otherwise skip to Question 105.</b>
104	Venous invasion type	<input type="checkbox"/> Extramural <input type="checkbox"/> Intramural <input type="checkbox"/> Unknown	6036344	Identify the location of vascular involvement for the tumor.
105	Lymphatic invasion present?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	64171	Indicate if malignant cells are present in small or thin-walled vessels, suggesting lymphatic involvement.
106	Perineural invasion present?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	64181	Indicate if perineural invasion or infiltration of tumor or cancer is present.
107	Number of positive lymph nodes	_____	89	Provide the number of lymph nodes involved with disease as determined by pathologic examination.
108	Number of lymph nodes examined	_____	3	Provide the number of lymph nodes removed and pathologically assessed for disease.
109	Margins of surgical resection	<input type="checkbox"/> R0 <input type="checkbox"/> RX <input type="checkbox"/> R1 <input type="checkbox"/> Not evaluated <input type="checkbox"/> R2	2608702	Indicate the status of the tissue margins following surgical resection of the tumor submitted for HCMI.
<b>Additional Metastatic/Recurrent Tumor Biospecimen Information (if applicable)</b>				
110	Are you submitting an additional metastatic/recurrent tumor tissue sample?	<input type="checkbox"/> Yes <input type="checkbox"/> 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. <b>Note: If yes, proceed to Question 111, otherwise, skip to Question 135.</b>
111	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.
112	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.
113	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.
114	Metastatic/ recurrent tumor tissue sample preservation method	<input type="checkbox"/> Cryopreserved <input type="checkbox"/> OCT <input type="checkbox"/> FFPE <input type="checkbox"/> Snap frozen <input type="checkbox"/> Frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
115	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.

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Tissue Source Site (TSS) Name: \_\_\_\_\_ HCMI Identifier (ID3): \_\_\_\_\_  
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
116	Method of metastatic/ recurrent cancer sample procurement	<input type="checkbox"/> Ampullectomy <input type="checkbox"/> Pancreaticoduodenectomy <input type="checkbox"/> Other (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. <b>Note: If the method of procurement is not listed, proceed to Question 116a, otherwise, skip to Question 117.</b>
116a	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.
117	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.
118	Metastatic/ recurrent site	<input type="checkbox"/> Ampulla of Vater <input type="checkbox"/> Bone <input type="checkbox"/> Brain <input type="checkbox"/> Kidney <input type="checkbox"/> Liver <input type="checkbox"/> Lung <input type="checkbox"/> Lymph node(s) distant <input type="checkbox"/> Lymph node(s) regional <input type="checkbox"/> Peritoneum <input type="checkbox"/> Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. <b>Note: If the metastatic/recurrent site is not listed, proceed to Question 118a, otherwise, skip to Question 119.</b>
118a	Other metastatic/ recurrent site	<input type="checkbox"/> Abdomen <input type="checkbox"/> Accessory sinus <input type="checkbox"/> Adrenal gland <input type="checkbox"/> Anus <input type="checkbox"/> Appendix <input type="checkbox"/> Bladder <input type="checkbox"/> Bone <input type="checkbox"/> Breast <input type="checkbox"/> Connective, subcutaneous and other soft tissues <input type="checkbox"/> Esophagus <input type="checkbox"/> Eye <input type="checkbox"/> Gallbladder <input type="checkbox"/> Gum <input type="checkbox"/> Head, face or neck <input type="checkbox"/> Heart <input type="checkbox"/> Kidney <input type="checkbox"/> Larynx <input type="checkbox"/> Lip <input type="checkbox"/> Liver <input type="checkbox"/> Lung <input type="checkbox"/> Lymph node <input type="checkbox"/> Male genital organs <input type="checkbox"/> Mediastinum <input type="checkbox"/> Meninges <input type="checkbox"/> Mouth <input type="checkbox"/> Nasal cavity <input type="checkbox"/> Nasopharynx <input type="checkbox"/> Nervous system <input type="checkbox"/> Oropharynx <input type="checkbox"/> Other ill-defined sites <input type="checkbox"/> Ovary <input type="checkbox"/> Palate <input type="checkbox"/> Pancreas <input type="checkbox"/> Penis <input type="checkbox"/> Peripheral nerves and autonomic nervous system of trunk <input type="checkbox"/> Peritoneum <input type="checkbox"/> Pharynx <input type="checkbox"/> Pituitary gland <input type="checkbox"/> Prostate gland <input type="checkbox"/> Rectosigmoid junction <input type="checkbox"/> Renal pelvis <input type="checkbox"/> Retroperitoneum <input type="checkbox"/> Skin <input type="checkbox"/> Small intestine <input type="checkbox"/> Spinal cord <input type="checkbox"/> Spleen <input type="checkbox"/> Stomach <input type="checkbox"/> Testis <input type="checkbox"/> Thymus <input type="checkbox"/> Thyroid gland <input type="checkbox"/> Tongue <input type="checkbox"/> Tonsil <input type="checkbox"/> Trachea <input type="checkbox"/> Unknown primary <input type="checkbox"/> Urinary system <input type="checkbox"/> Uterus <input type="checkbox"/> Vagina <input type="checkbox"/> Vulva	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
119	Site of relapse	<input type="checkbox"/> Local <input type="checkbox"/> Regional <input type="checkbox"/> Distant <input type="checkbox"/> Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
120	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
121	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.
122	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.
123	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.
124	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.
125	Is the patient still receiving treatment?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
126	Disease status	<input type="checkbox"/> No evidence of disease <input type="checkbox"/> Progressive disease <input type="checkbox"/> Stable disease <input type="checkbox"/> Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
127	Tumor extension	<input type="checkbox"/> Carcinoma in situ/high-grade dysplasia <input type="checkbox"/> Tumor limited to ampulla of Vater or sphincter of Oddi <input type="checkbox"/> Tumor invades beyond sphincter of Oddi (perisphincteric invasion) <input type="checkbox"/> Tumor invades into duodenal submucosa <input type="checkbox"/> Tumor invades into muscularis propria of the duodenum <input type="checkbox"/> Tumor directly invades pancreas up to 0.5 cm <input type="checkbox"/> Tumor extends more than 0.5 cm into pancreas <input type="checkbox"/> Tumor extends into peripancreatic soft tissues <input type="checkbox"/> Tumor extends into periduodenal tissue <input type="checkbox"/> Tumor extends into duodenal serosa <input type="checkbox"/> Tumor invades other adjacent organs or structures other than pancreas (specify) <input type="checkbox"/> Cannot be assessed	6326086	Select all options that represent the extent to which the Ampulla of Vater tumor has invaded through the wall of an organ into surrounding organs and/or adjacent tissues.  <b>Note: If the tumor invades into other adjacent organs, proceed to Question 127a, otherwise skip to Question 128.</b>
127a	Tumor extension other structures	_____	64351	If the Ampulla of Vater tumor has invaded adjacent organs or structures other than the pancreas, please specify the organ(s).
128	Venous invasion present?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	64358	Indicate whether venous invasion was present in the tumor specimen.  <b>Note: If venous invasion was identified in the tumor specimen, proceed to Question 129, otherwise skip to Question 130.</b>

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
129	Venous invasion type	<input type="checkbox"/> Extramural <input type="checkbox"/> Intramural <input type="checkbox"/> Unknown	6036344	Identify the location of vascular involvement for the tumor.
130	Lymphatic invasion present?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	64171	Indicate if malignant cells are present in small or thin-walled vessels, suggesting lymphatic involvement.
131	Perineural invasion present?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	64181	Indicate if perineural invasion or infiltration of tumor or cancer is present.
132	Number of positive lymph nodes	_____	89	Provide the number of lymph nodes involved with disease as determined by pathologic examination.
133	Number of lymph nodes examined	_____	3	Provide the number of lymph nodes removed and pathologically assessed for disease.
134	Margins of surgical resection	<input type="checkbox"/> R0 <input type="checkbox"/> R1 <input type="checkbox"/> R2 <input type="checkbox"/> RX <input type="checkbox"/> Not evaluated	2608702	Indicate the status of the tissue margins following surgical resection of the tumor submitted for HCMI.
<b>Metastatic/Recurrent Tumor Model Information</b>				
135	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. <b>Note: The first biospecimen should be number "1," the second should be number "2," etc.</b>
136	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.
137	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.
138	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.
139	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
<b>Additional Metastatic/Recurrent Biospecimen Tumor Model Information (if applicable)</b>				
140	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. <b>Note: The first biospecimen should be number "1," the second should be number "2," etc.</b>
141	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.
142	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.
143	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.
144	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
<b>Other Biospecimen Information</b>				
145	Are you submitting an OTHER tissue sample?	<input type="checkbox"/> Yes <input type="checkbox"/> No		Indicate whether an OTHER tissue sample (e.g. pre-malignant, non-malignant, or dysplastic tissue, etc.) was collected for HCMI for this case. <b>Note: If yes, proceed to Question 146.</b>
146	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. <b>Note: The first biospecimen should be number "1," the second should be number "2," etc.</b>
147	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.
148	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.
149	OTHER tissue sample preservation method	<input type="checkbox"/> Cryopreserved <input type="checkbox"/> OCT <input type="checkbox"/> FFPE <input type="checkbox"/> Snap frozen <input type="checkbox"/> Frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
150	Other method of cancer sample procurement	<input type="checkbox"/> Ampullectomy <input type="checkbox"/> Pancreaticoduodenectomy <input type="checkbox"/> Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. <b>Note: If the method of procurement is not listed, proceed to Question 150a, otherwise, skip to Question 151.</b>
150a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
151	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.
152	Tissue type	<input type="checkbox"/> Non-malignant <input type="checkbox"/> Other (specify)	64784	Indicate the OTHER tissue type. <b>Note: If the OTHER tissue type is not listed, proceed to Question 152a, otherwise, skip to Question 153.</b>
152a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
153	Anatomic site of OTHER tissue	<input type="checkbox"/> Ampulla of Vater <input type="checkbox"/> Lung <input type="checkbox"/> Bone <input type="checkbox"/> Lymph node <input type="checkbox"/> Brain <input type="checkbox"/> Peritoneum <input type="checkbox"/> Kidney <input type="checkbox"/> Other (specify) <input type="checkbox"/> Liver	6696813	Select the site from which the OTHER tissue used to develop the model was derived. <b>Note: If the OTHER tissue site is not listed, proceed to Question 153a, otherwise, skip to Question 154.</b>
153a	Specify anatomic site of OTHER tissue	<input type="checkbox"/> Abdomen <input type="checkbox"/> Other ill-defined sites <input type="checkbox"/> Accessory sinus <input type="checkbox"/> Ovary <input type="checkbox"/> Adrenal gland <input type="checkbox"/> Palate <input type="checkbox"/> Anus <input type="checkbox"/> Pancreas <input type="checkbox"/> Appendix <input type="checkbox"/> Penis <input type="checkbox"/> Bladder <input type="checkbox"/> Peripheral nerves and autonomic nervous system of trunk <input type="checkbox"/> Bone <input type="checkbox"/> Peritoneum <input type="checkbox"/> Breast <input type="checkbox"/> Pharynx <input type="checkbox"/> Connective, subcutaneous	6584916	Specify the site of OTHER tissue, if not in the previous list.

**Enrollment: Ampulla of Vater**



Tissue Source Site (TSS) Name: \_\_\_\_\_ HCMI Identifier (ID3): \_\_\_\_\_  
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		and other soft tissues <input type="checkbox"/> Esophagus <input type="checkbox"/> Eye <input type="checkbox"/> Gallbladder <input type="checkbox"/> Gum <input type="checkbox"/> Head, face or neck <input type="checkbox"/> Heart <input type="checkbox"/> Kidney <input type="checkbox"/> Larynx <input type="checkbox"/> Lip <input type="checkbox"/> Liver <input type="checkbox"/> Lung <input type="checkbox"/> Lymph node <input type="checkbox"/> Male genital organs <input type="checkbox"/> Mediastinum <input type="checkbox"/> Meninges <input type="checkbox"/> Mouth <input type="checkbox"/> Nasal cavity <input type="checkbox"/> Nasopharynx <input type="checkbox"/> Nervous system <input type="checkbox"/> Oropharynx	<input type="checkbox"/> Pituitary gland <input type="checkbox"/> Prostate gland <input type="checkbox"/> Rectosigmoid junction <input type="checkbox"/> Renal pelvis <input type="checkbox"/> Retroperitoneum <input type="checkbox"/> Skin <input type="checkbox"/> Small intestine <input type="checkbox"/> Spinal cord <input type="checkbox"/> Spleen <input type="checkbox"/> Stomach <input type="checkbox"/> Testis <input type="checkbox"/> Thymus <input type="checkbox"/> Thyroid gland <input type="checkbox"/> Tongue <input type="checkbox"/> Tonsil <input type="checkbox"/> Trachea <input type="checkbox"/> Unknown primary <input type="checkbox"/> Urinary system <input type="checkbox"/> Uterus <input type="checkbox"/> Vagina <input type="checkbox"/> Vulva		
154	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.	
155	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.	
<b>Additional OTHER biospecimen Information (if applicable)</b>					
156	Are you submitting an additional OTHER tissue sample?	<input type="checkbox"/> Yes <input type="checkbox"/> No		Indicate whether an additional OTHER tissue sample (pre-malignant, non-malignant, or dysplastic tissue, etc.) is being submitted for HCMI for this case. <b>Note: If yes, proceed to Question 157. If no, proceed to Question 167.</b>	
157	OTHER tissue biospecimen ordinal	_____	6584267	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.	
158	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.	
159	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.	
160	OTHER tissue sample preservation method	<input type="checkbox"/> Cryopreserved <input type="checkbox"/> FFPE <input type="checkbox"/> Frozen <input type="checkbox"/> OCT <input type="checkbox"/> Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.	
161	Other method of cancer sample procurement	<input type="checkbox"/> Ampullectomy <input type="checkbox"/> Pancreaticoduodenectomy <input type="checkbox"/> Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. <b>Note: If the method of procurement is not listed, proceed to Question 161a, otherwise, skip to Question 162.</b>	

**Enrollment: Ampulla of Vater**



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
161a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
162	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.
163	Tissue type	<input type="checkbox"/> Non-malignant <input type="checkbox"/> Other (specify)	64784	Indicate the OTHER tissue type. <b>Note: If the OTHER tissue type is not listed, proceed to Question 163a, otherwise, skip to Question 164.</b>
163a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
164	Anatomic site of OTHER tissue	<input type="checkbox"/> Ampulla of Vater <input type="checkbox"/> Bone <input type="checkbox"/> Brain <input type="checkbox"/> Kidney <input type="checkbox"/> Liver <input type="checkbox"/> Lung <input type="checkbox"/> Lymph node <input type="checkbox"/> Peritoneum <input type="checkbox"/> Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. <b>Note: If the OTHER tissue site is not listed, proceed to Question 164a, otherwise, skip to Question 165.</b>
164a	Specify anatomic site of OTHER tissue	<input type="checkbox"/> Abdomen <input type="checkbox"/> Accessory sinus <input type="checkbox"/> Adrenal gland <input type="checkbox"/> Anus <input type="checkbox"/> Appendix <input type="checkbox"/> Bladder <input type="checkbox"/> Bone <input type="checkbox"/> Breast <input type="checkbox"/> Connective, subcutaneous and other soft tissues <input type="checkbox"/> Esophagus <input type="checkbox"/> Eye <input type="checkbox"/> Gallbladder <input type="checkbox"/> Gum <input type="checkbox"/> Head, face or neck <input type="checkbox"/> Heart <input type="checkbox"/> Kidney <input type="checkbox"/> Larynx <input type="checkbox"/> Lip <input type="checkbox"/> Liver <input type="checkbox"/> Lung <input type="checkbox"/> Lymph node <input type="checkbox"/> Male genital organs <input type="checkbox"/> Mediastinum <input type="checkbox"/> Meninges <input type="checkbox"/> Mouth <input type="checkbox"/> Nasal cavity <input type="checkbox"/> Nasopharynx <input type="checkbox"/> Nervous system <input type="checkbox"/> Oropharynx <input type="checkbox"/> Other ill-defined sites <input type="checkbox"/> Ovary <input type="checkbox"/> Palate <input type="checkbox"/> Pancreas <input type="checkbox"/> Penis <input type="checkbox"/> Peripheral nerves and autonomic nervous system of trunk <input type="checkbox"/> Peritoneum <input type="checkbox"/> Pharynx <input type="checkbox"/> Pituitary gland <input type="checkbox"/> Prostate gland <input type="checkbox"/> Rectosigmoid junction <input type="checkbox"/> Renal pelvis <input type="checkbox"/> Retroperitoneum <input type="checkbox"/> Skin <input type="checkbox"/> Small intestine <input type="checkbox"/> Spinal cord <input type="checkbox"/> Spleen <input type="checkbox"/> Stomach <input type="checkbox"/> Testis <input type="checkbox"/> Thymus <input type="checkbox"/> Thyroid gland <input type="checkbox"/> Tongue <input type="checkbox"/> Tonsil <input type="checkbox"/> Trachea <input type="checkbox"/> Unknown primary <input type="checkbox"/> Urinary system <input type="checkbox"/> Uterus <input type="checkbox"/> Vagina <input type="checkbox"/> Vulva	6584916	Specify the site of OTHER tissue, if not in the previous list.
165	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.



## Enrollment: Ampulla of Vater

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



Question	Question Text	Data Entry Options	CDE ID	Question Text
166	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.
<b>Other Tissue Model Information</b>				
167	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. <b>Note: The first biospecimen should be number "1," the second should be number "2," etc.</b>
168	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.
169	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.
170	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
171	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.
<b>Additional Other Tissue Model Information (if applicable)</b>				
172	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. <b>Note: The first biospecimen should be number "1," the second should be number "2," etc.</b>
173	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.
174	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.
175	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
176	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.