

## Enrollment: Ampulla of Vater Cancer

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>Normal Control Information</b>				
4	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.
5	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 normal tissue was not submitted, select 'Not applicable'. If the anatomic site of normal tissue is not listed, proceed to Question 5a, otherwise, skip to Question 6.</b>
5a	Other anatomic site of normal tissue	_____	3288189	If the site of the normal tissue was not provided on the provided list, please specify the anatomic site.
6	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>
<b>Tumor Tissue Collected for Molecular Characterization, Sample Information</b>				
7	Tumor tissue sample preservation method	<input type="checkbox"/> FFPE <input type="checkbox"/> Fresh <input type="checkbox"/> OCT <input type="checkbox"/> Snap frozen	5432521	Provide the method used to preserve the tumor tissue sample collected to be used for molecular characterization.
<b>Cancer Model Information</b>				
8	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)	4214629	Indicate the anatomic site of the tumor tissue used to generate the model for the HCMI. <b>Note: If the anatomic site of tumor tissue is not listed, proceed to Question 8a, otherwise, skip to Question 9.</b>
8a	Other anatomic site	_____	5946219	If the anatomic site for the tumor submitted to HCMI is not included on the provided list, specify the anatomic site.

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9	Method of cancer sample procurement	<input type="checkbox"/> Ampullectomy <input type="checkbox"/> Pancreaticoduodenectomy <input type="checkbox"/> Other (specify)	3103514	Indicate the procedure performed to obtain the tumor tissue used to generate the model for HCMI. <b>Note: If the method of sample procurement is not listed, proceed to Question 9a, otherwise, skip to Question 10.</b>
9a	Other method of sample procurement	_____	2006730	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
10	Number of days from index date to date of cancer sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the tumor tissue submitted for HCMI.
11	ICD-10 code for model tumor	<input type="checkbox"/> C24.1 <input type="checkbox"/> C79.0 <input type="checkbox"/> C77.9 <input type="checkbox"/> C79.3 <input type="checkbox"/> C78.0 <input type="checkbox"/> C79.5 <input type="checkbox"/> C78.6 <input type="checkbox"/> Other (specify) <input type="checkbox"/> C78.7	3226287	Provide the ICD-10 code for the tumor used to generate the model submitted to HCMI. <b>Note: If the ICD-10 code is not listed, proceed to Question 11a, otherwise, skip to Question 12.</b>
11a	Other ICD-10 code	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.
12	Tumor tissue type	<input type="checkbox"/> Premalignant <input type="checkbox"/> Primary <input type="checkbox"/> Recurrent <input type="checkbox"/> Metastatic <input type="checkbox"/> Additional primary <input type="checkbox"/> NOS	3288124	Provide the tumor tissue type for the biospecimen used to produce the model for the HCMI. <b>Note: If 'Metastatic' is selected, continue to answer through Question 20. If the tissue is not 'Metastatic', skip to Question 21.</b>
<b>Metastatic Model Information</b> (only complete Questions 13-20 if 'Metastatic' was selected in Question 12)				
13	Age at diagnosis of metastasis	_____	6032752	Provide the age (in days) of the patient when diagnosed with metastatic disease. If the patient's age is greater than 32,507 days (89 years), please enter 32,507.
14	Number of days from index date to date of diagnosis of metastasis	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic disease.
15	Metastatic site	<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)	6119068	Select the site from which the metastatic tissue used to develop the model was derived. <b>Note: If the metastatic site is not listed, proceed to Question 15a, otherwise, skip to Question 16.</b>
15a	Other metastatic site	_____	3128033	If not included in the previous list, specify the site from which the metastatic tissue used to develop the model was derived.
16	Maintenance and/or consolidation therapy administered prior to collection of metastatic tissue	_____	6119066	If applicable, provide the name of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic tissue used to develop the model. <b>Note: If maintenance and/or consolidation therapy was not administered, skip to Question 21.</b>

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17	Days from index date to start of maintenance and/or consolidation therapy	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
18	Days from index date to last known date of maintenance and/or consolidation therapy treatment	_____	65167	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy treatment.
19	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 treatment.
20	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.
<b>Patient Information</b>				
21	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.
22	Height	_____	649	Provide the patient's height, in centimeters.
23	Weight	_____	651	Provide the patient's weight, in kilograms.
24	Body mass index (BMI)	_____	2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
25	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 allowed to collect	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 Phillipine 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.
26	Ethnicity	<input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Unknown <input type="checkbox"/> Not allowed to collect	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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27	Year of birth	_____	2896954	Provide the year of the patient's birth. If the patient was born prior to 1928, insert the date 1928.
28	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?
29	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.
<b>Primary Tumor Diagnosis Information</b>				
30	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.
31	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. If the patient's age is greater than 32,507 days (89 years), please enter 32,507.
32	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 morphology is not listed, proceed to Question 32a, otherwise, skip to Question 33.</b>
32a	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.
33	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 tissue or organ of origin is not listed, proceed to Question 33a, otherwise, skip to Question 34.</b>

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33a	Other tissue or organ of origin	<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	3427536	If the primary site of the disease is not included on the previous list, select the primary site of the disease.
34	Histological type	<input type="checkbox"/> Cancer of the ampulla of Vater <input type="checkbox"/> Other (specify) _____	3081932	Provide the traditional surgical pathology text description of the histological tumor type. <b>Note: If the histological type is not listed, proceed to Question 34a, otherwise, skip to Question 35.</b>
34a	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.
35	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 35a, otherwise, skip to Question 36.</b> <b>If the histological subtype is Adenocarcinoma, proceed to Question 36.</b> <b>If the histological subtype is adenocarcinoma with peculiar aspects, proceed to Question 37, otherwise skip to 38.</b>

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
35a	Other histological subtype	_____	3124492	If the histological subtype for the primary tumor is not included in the provided list, specify the histological subtype.
36	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.
37	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.
38	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.
39	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.
40	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.
41	AJCC cancer staging edition	<input type="checkbox"/> 1 <sup>st</sup> <input type="checkbox"/> 5 <sup>th</sup> <input type="checkbox"/> 2 <sup>nd</sup> <input type="checkbox"/> 6 <sup>th</sup> <input type="checkbox"/> 3 <sup>rd</sup> <input type="checkbox"/> 7 <sup>th</sup> <input type="checkbox"/> 4 <sup>th</sup> <input type="checkbox"/> 8 <sup>th</sup>	2722309	Select the AJCC staging handbook edition used to stage the patient.
42	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).
43	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).
44	Pathologic spread: Lymph nodes (pN)	<input type="checkbox"/> N0 <input type="checkbox"/> N2 <input type="checkbox"/> N1 <input type="checkbox"/> NX	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).
45	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).
46	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	3203222	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).
47	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.



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48	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.
49	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 all the site(s) of metastasis at the time of diagnosis of the primary tumor. <b>Note: If the metastatic site(s) is not listed, proceed to Question 49a, otherwise, skip to Question 50.</b>
49a	Specify metastatic site(s)	_____	3128033	If the site of metastasis is not included on the provided list, specify the site of metastasis.
50	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, select all sites of relapse. <b>Note: If the primary tumor did not relapse, select 'Not applicable'.</b>
<b>Prognostic/Predictive/Lifestyle Features for Tumor Prognosis or Responsiveness to Treatment</b>				
51	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 51a, otherwise skip to Question 52.</b>
51a	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).
52	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 53, otherwise skip to Question 54.</b>
53	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.
54	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.
55	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.
56	Number of positive lymph nodes	_____	89	Provide the number of lymph nodes involved with disease as determined by pathologic examination.
57	Number of lymph nodes examined	_____	3	Provide the number of lymph nodes removed and pathologically assessed for disease.

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58	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>Treatment Information</b>				
59	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: Radiation therapy is addressed in Questions 69-70. Pharmaceutical therapy is addressed in Questions 60-68.</b>
60	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 61-62. Hormonal therapy is addressed in Questions 63-64. Immunotherapy is addressed in Questions 65-66. Targeted therapy is addressed in Questions 67-68.</b>
61	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 63. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 61a, otherwise, skip to Question 62.</b>
61a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapy.
62	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.
63	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 63a, otherwise, skip to Question 64.</b>
63a	Other hormone therapy	_____	2405358	If the hormone therapy is not included in the provided list, specify hormone therapy.
64	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.
65	Immunotherapy	<input type="checkbox"/> Atezolizumab <input type="checkbox"/> Avelumab <input type="checkbox"/> Durvalumab <input type="checkbox"/> Nivolumab <input type="checkbox"/> Pembrolizumab <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 65a, otherwise, skip to Question 66.</b>
65a	Other immunotherapy	_____	2953828	If the immunotherapy is not included in the provided list, specify immunotherapy.
66	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.



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 Completed By: \_\_\_\_\_ Completion Date (MM/DD/YYYY): \_\_\_\_\_



Question	Question Text	Data Entry Options	CDE ID	Instruction Text
67	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 67a, otherwise, skip to Question 68.</b>
67a	Other targeted therapy	_____	4308476	If the targeted therapy is not included in the provided list, specify targeted therapy.
68	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.
69	Radiation therapy administered type	<input type="checkbox"/> 2D conventional <input type="checkbox"/> 3D conformal <input type="checkbox"/> Brachytherapy HDR <input type="checkbox"/> Brachytherapy LDR <input type="checkbox"/> IMRT <input type="checkbox"/> Proton Beam <input type="checkbox"/> Stereotactic Body RT <input type="checkbox"/> Stereotactic Radiosurgery <input type="checkbox"/> WBRT <input type="checkbox"/> Other (specify) <input type="checkbox"/> Unspecified <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, skip the remaining questions. If the radiation therapy is not listed, proceed to Question 69a, otherwise, skip to Question 70.</b>
69a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
70	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.