

## Enrollment: Pancreas

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"/> Gastrointestinal <input type="checkbox"/> Pancreas <input type="checkbox"/> Skin <input type="checkbox"/> Spleen <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"/> Pancreatic body <input type="checkbox"/> Pancreatic head <input type="checkbox"/> Pancreatic tail <input type="checkbox"/> Liver <input type="checkbox"/> Lung <input type="checkbox"/> Lymph node <input type="checkbox"/> Peritoneum <input type="checkbox"/> Other (specify)	5984812	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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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
9	Method of cancer sample procurement	<input type="checkbox"/> Whipple procedure <input type="checkbox"/> Distal partial pancreatectomy <input type="checkbox"/> Fine needle aspiration biopsy <input type="checkbox"/> Core needle biopsy <input type="checkbox"/> Paracentesis <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"/> C25.0 <input type="checkbox"/> C25.8 <input type="checkbox"/> C25.1 <input type="checkbox"/> C25.9 <input type="checkbox"/> C25.2 <input type="checkbox"/> C78.0 <input type="checkbox"/> C25.3 <input type="checkbox"/> C78.6 <input type="checkbox"/> C25.4 <input type="checkbox"/> C78.7 <input type="checkbox"/> C25.7 <input type="checkbox"/> Other (specify)	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"/> Lung <input type="checkbox"/> Liver <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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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
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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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
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"/> 8490/3 <input type="checkbox"/> 8020/3 <input type="checkbox"/> 8500/3 <input type="checkbox"/> 8035/3 <input type="checkbox"/> 8510/3 <input type="checkbox"/> 8041/3 <input type="checkbox"/> 8550/3 <input type="checkbox"/> 8246/3 <input type="checkbox"/> 8551/3 <input type="checkbox"/> 8441/3 <input type="checkbox"/> 8560/3 <input type="checkbox"/> 8452/3 <input type="checkbox"/> 8576/3 <input type="checkbox"/> 8453/3 <input type="checkbox"/> 8971/3 <input type="checkbox"/> 8470/3 <input type="checkbox"/> Other (specify) <input type="checkbox"/> 8480/3	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"/> Pancreas <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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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
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"/> Pancreatic carcinoma <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.

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
35	Histological subtype	<input type="checkbox"/> Acinar cell carcinoma <input type="checkbox"/> Acinar cell cystadenocarcinoma <input type="checkbox"/> Adenocarcinoma ductal type <input type="checkbox"/> Hepatoid carcinoma <input type="checkbox"/> High-grade neuroendocrine carcinoma (large cell type) <input type="checkbox"/> High-grade neuroendocrine carcinoma (small cell type) <input type="checkbox"/> Inflammatory myofibroblastic tumor <input type="checkbox"/> Intraductal papillary mucinous neoplasm (IPMN, main duct/mixed) <input type="checkbox"/> Intraductal papillary mucinous neoplasm (IPMN, side duct) <input type="checkbox"/> Invasive adenocarcinoma arising from IPMN <input type="checkbox"/> Invasive carcinoma arising in MCN <input type="checkbox"/> Medullary carcinoma <input type="checkbox"/> Mixed acinar-ductal carcinomas <input type="checkbox"/> Mixed acinar-neuroendocrine carcinoma <input type="checkbox"/> Mixed ductal-neuroendocrine carcinoma <input type="checkbox"/> Mucinous cystic neoplasms (MCN) <input type="checkbox"/> Pancreas colloid (mucinous non-cystic) carcinoma <input type="checkbox"/> Pancreatoblastoma <input type="checkbox"/> Serous cystic adenoma (SCA) <input type="checkbox"/> Signet ring cell carcinoma <input type="checkbox"/> Solid pseudopapillary neoplasm <input type="checkbox"/> Undifferentiated (anaplastic) carcinoma <input type="checkbox"/> Undifferentiated carcinoma with osteoclast-like giant cells <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>
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	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.
37	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.
38	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.
39	Clinical stage group	<input type="checkbox"/> Stage 0 <input type="checkbox"/> Stage IIB <input type="checkbox"/> Stage IA <input type="checkbox"/> Stage III <input type="checkbox"/> Stage IB <input type="checkbox"/> Stage IV <input type="checkbox"/> Stage IIA	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).
40	Pathologic spread: Primary tumor (pT)	<input type="checkbox"/> T0 <input type="checkbox"/> T1b <input type="checkbox"/> T3 <input type="checkbox"/> Tis <input type="checkbox"/> T1c <input type="checkbox"/> T4 <input type="checkbox"/> T1 <input type="checkbox"/> T2 <input type="checkbox"/> TX <input type="checkbox"/> T1a	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).
41	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).

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42	Pathologic spread: Distant metastases (pM)	<input type="checkbox"/> M0 <input type="checkbox"/> M1 <input type="checkbox"/> M1a <input type="checkbox"/> M1b <input type="checkbox"/> M1c	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).
43	Tumor stage (pathological)	<input type="checkbox"/> Stage 0 <input type="checkbox"/> Stage I <input type="checkbox"/> Stage IA <input type="checkbox"/> Stage IB <input type="checkbox"/> Stage IIA <input type="checkbox"/> Stage IIB <input type="checkbox"/> Stage III <input type="checkbox"/> Stage IV	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).
44	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.
45	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.
46	Metastatic site(s) at diagnosis	<input type="checkbox"/> Lung <input type="checkbox"/> Liver <input type="checkbox"/> Peritoneum <input type="checkbox"/> Other (specify)	3108271	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 46a, otherwise, skip to Question 47.</b>
46a	Specify metastatic site(s)	_____	3128033	If the site of metastasis is not included on the provided list, specify the site of metastasis.
47	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>				
48	Number of peripancreatic lymph nodes tested at surgery	_____	6050944	Provide the total number of peripancreatic lymph nodes tested for the presence of pancreatic cancer cells.
49	Number of positive peripancreatic lymph nodes	<input type="checkbox"/> 0 <input type="checkbox"/> 1-3 <input type="checkbox"/> ≥4 <input type="checkbox"/> Unknown	5983082	Select the numeric range of the number of peripancreatic lymph nodes that tested positive for the presence of pancreatic cancer cells.
50	Alcohol exposure intensity	<input type="checkbox"/> Lifelong non-drinker <input type="checkbox"/> Non-drinker <input type="checkbox"/> Occasional drinker <input type="checkbox"/> Drinker <input type="checkbox"/> Heavy drinker <input type="checkbox"/> Not evaluated	3457767	Select the patient's current level of alcohol use as self-reported by the patient.
51	Amount of alcohol consumption per week	_____	3114013	Provide the average number of days each week that the patient consumes an alcoholic beverage.
52	History of diabetes	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	3197322	Indicate whether the patient has a diagnosis of diabetes. <b>Note: If the patient does not have a history of diabetes, skip to Question 54.</b>
53	Diabetes treatment	<input type="checkbox"/> Injected insulin <input type="checkbox"/> Biguanide <input type="checkbox"/> Sulfonylurea <input type="checkbox"/> Thiazolidinedione <input type="checkbox"/> Alpha-glucosidase inhibitor <input type="checkbox"/> Other (specify)	3587247	Select all diabetes mellitus treatments given to the patient. <b>Note: If the diabetes treatment is not listed, proceed to Question 53a, otherwise, skip to Question 54.</b>

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53a	Other diabetes treatment	_____	3587240	If the patient's diabetes treatment is not included on the previous list, provide the name of the other diabetes treatment.
54	Prior clinical history, if known	<input type="checkbox"/> IPMN <input type="checkbox"/> Chronic pancreatitis <input type="checkbox"/> Neuroendocrine tumor <input type="checkbox"/> Adenocarcinoma <input type="checkbox"/> Not applicable	5983086	Provide the patient's clinical history that may increase risk of pancreatic cancer.
55	Basis of diagnosis of prior clinical history	<input type="checkbox"/> Histologic <input type="checkbox"/> Pathologic <input type="checkbox"/> Radiologic <input type="checkbox"/> Not applicable	5946730	Select the method used to determine the diagnosis of prior clinical history.
56	History of clinical chronic pancreatitis	<input type="checkbox"/> Yes <input type="checkbox"/> No	3457760	Indicate whether or not the patient has a history of clinical chronic pancreatitis. <b>Note: If the patient does not have a history of chronic pancreatitis, skip to Question 58.</b>
57	Year of chronic pancreatitis diagnosis	_____	3457763	Provide the year that the patient was diagnosed with clinical chronic pancreatitis.
58	Has the CEA level of the patient been determined?	<input type="checkbox"/> Yes <input type="checkbox"/> No	3107563	Indicate whether the Carcinoembryonic antigen (CEA) level of the patient has been determined. <b>Note: If the patient's CEA level has not been determined, skip to Question 61.</b>
59	CEA level	_____	2752	Provide the patient's carcinoembryonic (CEA) level (ng/ml).
60	CEA level upper limit of normal value	_____	2002247	Provide the numeric laboratory value (ng/ml) representing the upper level of the normal range of values for carcinoembryonic antigen (CEA) in blood used to comparatively reference the patient's lab result.
61	Was tumor marker CA-19-9 test performed?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	2891778	Indicate whether the patient's tumor marker CA-19-9 value was assessed. <b>Note: If the CA-19-9 test was not performed, skip to Question 63.</b>
62	What was the CA-19-9 value?	_____	65302	Provide the patient's CA-19-9 level.
63	Was KRAS mutation analysis performed?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	6060079	Indicate whether KRAS mutation analysis was performed. <b>Note: If not performed, skip to Question 66.</b>
64	Was a mutation in KRAS identified	<input type="checkbox"/> Yes <input type="checkbox"/> No	6060081	Indicate whether a mutation in KRAS was identified through mutation analysis. <b>Note: If mutation was not identified, skip to Question 66.</b>
65	If KRAS mutation identified, which one?	<input type="checkbox"/> G12A <input type="checkbox"/> G13C <input type="checkbox"/> G12C <input type="checkbox"/> G13A <input type="checkbox"/> G12D <input type="checkbox"/> G13V <input type="checkbox"/> G12R <input type="checkbox"/> Q61L <input type="checkbox"/> G12S <input type="checkbox"/> Q61H <input type="checkbox"/> G12V <input type="checkbox"/> A146T <input type="checkbox"/> G13D <input type="checkbox"/> Other (specify) <input type="checkbox"/> G13R	6060083	Indicate the specific KRAS mutation identified. <b>Note: If the KRAS mutation is not listed, proceed to Question 65a, otherwise, skip to Question 66.</b>
65a	Other KRAS mutation(s)	_____	6101691	If the KRAS mutation identified is not provided in the previous list, specify the KRAS mutation.
66	Was TP53 mutation analysis performed?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	6063448	Indicate whether TP53 mutation analysis was performed. <b>Note: If not performed, skip to Question 69.</b>



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67	Was a mutation in TP53 identified?	<input type="checkbox"/> Yes <input type="checkbox"/> No	6063523	Indicate whether a mutation in TP53 was identified through mutation analysis. <b>Note: If mutation was not identified, skip to Question 69.</b>
68	If TP53 mutation identified, which one?	<input type="checkbox"/> R175H <input type="checkbox"/> R213L <input type="checkbox"/> Y220C <input type="checkbox"/> C238Y <input type="checkbox"/> G245D <input type="checkbox"/> G245S <input type="checkbox"/> R248Q <input type="checkbox"/> R248W <input type="checkbox"/> G266E <input type="checkbox"/> G266V <input type="checkbox"/> V272M <input type="checkbox"/> R273C <input type="checkbox"/> R273H <input type="checkbox"/> R273L <input type="checkbox"/> R282G <input type="checkbox"/> R282W <input type="checkbox"/> Other (specify)	6063731	Indicate the specific TP53 mutation identified. <b>Note: If the TP53 mutation is not listed, proceed to Question 68a, otherwise, skip to Question 69.</b>
68a	Other TP53 mutation(s)	_____	6101683	If the TP53 mutation identified is not provided in the previous list, specify the TP53 mutation.
69	Was CDKN2A mutation analysis performed?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	6063449	Indicate whether CDKN2A mutation analysis was performed. <b>Note: If not performed, skip to Question 72.</b>
70	Was a mutation in CDKN2A identified?	<input type="checkbox"/> Yes <input type="checkbox"/> No	6063534	Indicate whether a mutation in CDKN2A was identified through mutation analysis. <b>Note: If mutation was not identified, skip to Question 72.</b>
71	If CDKN2A mutation identified, which one?	<input type="checkbox"/> A30V <input type="checkbox"/> V51D <input type="checkbox"/> V51I <input type="checkbox"/> H83P <input type="checkbox"/> H83Y <input type="checkbox"/> D108H <input type="checkbox"/> D108Y <input type="checkbox"/> L130Q <input type="checkbox"/> A147T <input type="checkbox"/> A148T <input type="checkbox"/> Other (specify)	6063732	Indicate the specific CDKN2A mutation identified. <b>Note: If the CDKN2A mutation is not listed, proceed to Question 71a, otherwise, skip to Question 72.</b>
71a	Other CDKN2A mutation(s)	_____	6101684	If the CDKN2A mutation identified is not provided in the previous list, specify the CDKN2A mutation.
72	Was GNAS mutation analysis performed?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	6063450	Indicate whether GNAS mutation analysis was performed. <b>Note: If not performed, skip to Question 75.</b>
73	Was a mutation in GNAS identified?	<input type="checkbox"/> Yes <input type="checkbox"/> No	5983161	Indicate whether a mutation in GNAS was identified through mutation analysis. <b>Note: If mutation was not identified, skip to Question 75.</b>
74	If GNAS mutation identified, which one?	<input type="checkbox"/> Q125R <input type="checkbox"/> R160C <input type="checkbox"/> R201C <input type="checkbox"/> R201H <input type="checkbox"/> R201S <input type="checkbox"/> Q227E <input type="checkbox"/> Q227L <input type="checkbox"/> Q227P <input type="checkbox"/> Q227R <input type="checkbox"/> Other (specify)	6063733	Indicate the specific GNAS mutation identified. <b>Note: If the GNAS mutation is not listed, proceed to Question 74a, otherwise, skip to Question 75.</b>
74a	Other GNAS mutation(s)	_____	6101685	If the GNAS mutation identified is not provided in the previous list, specify the GNAS mutation.
75	Was RNF43 mutation analysis performed?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	6063451	Indicate whether RNF43 mutation analysis was performed. <b>Note: If not performed, skip to Question 78.</b>

## Enrollment: Pancreas

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
76	Was a mutation in RNF43 identified?	<input type="checkbox"/> Yes <input type="checkbox"/> No	5983286	Indicate whether a mutation in RNF43 was identified through mutation analysis. <b>Note: If mutation was not identified, skip to Question 78.</b>
77	If RNF43 mutation identified, which one?	<input type="checkbox"/> R127P <input type="checkbox"/> A169T <input type="checkbox"/> D140E <input type="checkbox"/> E318D <input type="checkbox"/> P154L <input type="checkbox"/> Other (specify)	6063734	Indicate the specific RNF43 mutation identified. <b>Note: If the RNF43 mutation is not listed, proceed to Question 77a, otherwise, skip to Question 78.</b>
77a	Other RNF43 mutation(s)	_____	6101686	If the RNF43 mutation identified is not provided in the previous list, specify the RNF43 mutation.
78	Was SMAD4 IHC performed?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	6063646	Indicate whether SMAD4 protein expression by immunohistochemistry (IHC) analysis was performed. <b>Note: If not performed, skip to Question 80.</b>
79	SMAD4 expression by IHC	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Equivocal	6063676	Indicate the status of SMAD4 protein expression as determined by immunohistochemistry (IHC).
<b>Treatment Information</b>				
80	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 88-89. Pharmaceutical therapy is addressed in Questions 81-87.</b>
81	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 82-83. Immunotherapy is addressed in Questions 84-85. Targeted therapy is addressed in Questions 86-87.</b>
82	Neoadjuvant chemotherapeutic regimen	<input type="checkbox"/> 5-Fluorouracil <input type="checkbox"/> Albumin-bound paclitaxel <input type="checkbox"/> Capecitabine <input type="checkbox"/> Cisplatin <input type="checkbox"/> Docetaxel <input type="checkbox"/> Folfirinox (Oxaliplatin + Leucovorin + Irinotecan + 5-FU) <input type="checkbox"/> Gemcitabine <input type="checkbox"/> Gemcitabine abraxane <input type="checkbox"/> Irinotecan <input type="checkbox"/> Irinotecan liposome <input type="checkbox"/> Oxaliplatin <input type="checkbox"/> Paclitaxel <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 84. If the neoadjuvant chemotherapeutic treatment is not listed, proceed to Question 82a, otherwise, skip to Question 83.</b>
82a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapy.
83	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.

## Enrollment: Pancreas

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
84	Immunotherapy	_____	2185614	Specify the name of the immunotherapy administered. <b>Note: If immunotherapy was not administered, skip to Question 86.</b>
85	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
86	Targeted therapy	<input type="checkbox"/> Erlotinib <input type="checkbox"/> Other (specify)	5983083	Select the targeted therapy administered to the patient. <b>Note: If targeted therapy was not administered, skip to Question 88. If the targeted therapy is not listed, proceed to Question 86a, otherwise, skip to Question 87.</b>
86a	Other targeted therapy	_____	4308476	If the targeted therapy is not included in the provided list, specify targeted therapy.
87	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.
88	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 88a, otherwise, skip to Question 89.</b>
88a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
89	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.