

## Enrollment: Colon/Rectum

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



**Form Notes:** An Enrollment Form should be completed for each HCM 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 HCM-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 HCM 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"/> Ascending colon <input type="checkbox"/> Cecum <input type="checkbox"/> Descending colon <input type="checkbox"/> Hepatic flexure <input type="checkbox"/> Rectosigmoid junction <input type="checkbox"/> Rectum <input type="checkbox"/> Sigmoid colon <input type="checkbox"/> Splenic flexure <input type="checkbox"/> Transverse colon <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"/> Ascending colon <input type="checkbox"/> Ascending colon hepatic flexure <input type="checkbox"/> Cecum <input type="checkbox"/> Descending colon <input type="checkbox"/> Ileocecal valve <input type="checkbox"/> Rectosigmoid junction <input type="checkbox"/> Rectum <input type="checkbox"/> Sigmoid colon <input type="checkbox"/> Splenic flexure <input type="checkbox"/> Transverse colon <input type="checkbox"/> Brain <input type="checkbox"/> Liver <input type="checkbox"/> Lung <input type="checkbox"/> Lymph node <input type="checkbox"/> Peritoneum <input type="checkbox"/> Other (specify)	6033148	Indicate the anatomic site of the tumor tissue used to generate the model for the HCM. <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 HCM is not included on the provided list, specify the anatomic site.

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9	Method of cancer sample procurement	<input type="checkbox"/> Abdomino-perineal resection <input type="checkbox"/> Anterior resection of rectum <input type="checkbox"/> Endo-rectal tumor resection <input type="checkbox"/> Left hemicolectomy <input type="checkbox"/> Pan-proto colectomy <input type="checkbox"/> Right hemicolectomy <input type="checkbox"/> Sigmoid colectomy <input type="checkbox"/> Total colectomy <input type="checkbox"/> Transverse colectomy <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"/> C18.0 <input type="checkbox"/> C18.9 <input type="checkbox"/> C18.1 <input type="checkbox"/> C19 <input type="checkbox"/> C18.2 <input type="checkbox"/> C20 <input type="checkbox"/> C18.3 <input type="checkbox"/> C77.9 <input type="checkbox"/> C18.4 <input type="checkbox"/> C78.0 <input type="checkbox"/> C18.5 <input type="checkbox"/> C78.6 <input type="checkbox"/> C18.6 <input type="checkbox"/> C78.7 <input type="checkbox"/> C18.7 <input type="checkbox"/> C79.3 <input type="checkbox"/> C18.8 <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"/> Liver <input type="checkbox"/> Peritoneum <input type="checkbox"/> Lung <input type="checkbox"/> Lymph nodes <input type="checkbox"/> Brain <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.

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
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>
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.
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.

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
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.
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"/> 8246/3 <input type="checkbox"/> 8020/3 <input type="checkbox"/> 8480/3 <input type="checkbox"/> 8032/3 <input type="checkbox"/> 8490/3 <input type="checkbox"/> 8041/3 <input type="checkbox"/> 8510/3 <input type="checkbox"/> 8070/3 <input type="checkbox"/> 8560/3 <input type="checkbox"/> 8140/3 <input type="checkbox"/> Other (specify) <input type="checkbox"/> 8213/0	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"/> Colon <input type="checkbox"/> Rectum <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"/> Colon cancer <input type="checkbox"/> Colorectal cancer <input type="checkbox"/> Rectal cancer <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"/> Adenosquamous carcinoma <input type="checkbox"/> Large cell neuroendocrine carcinoma <input type="checkbox"/> Medullary carcinoma <input type="checkbox"/> Micropapillary carcinoma <input type="checkbox"/> Mucinous adenocarcinoma <input type="checkbox"/> Neuroendocrine carcinoma (poorly differentiated) <input type="checkbox"/> Serrated adenocarcinoma <input type="checkbox"/> Signet ring cell carcinoma <input type="checkbox"/> Small cell neuroendocrine carcinoma <input type="checkbox"/> Squamous cell carcinoma <input type="checkbox"/> Undifferentiated carcinoma <input type="checkbox"/> Carcinoma; type cannot be determined <input type="checkbox"/> Other (specify) _____	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>

## Enrollment: Colon/Rectum

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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	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 IIIB <input type="checkbox"/> Stage I <input type="checkbox"/> Stage IIIC <input type="checkbox"/> Stage IIA <input type="checkbox"/> Stage IVA <input type="checkbox"/> Stage IIB <input type="checkbox"/> Stage IVB <input type="checkbox"/> Stage IIC <input type="checkbox"/> Stage IVC <input type="checkbox"/> Stage IIIA	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"/> T2 <input type="checkbox"/> T4a <input type="checkbox"/> Tis <input type="checkbox"/> T3 <input type="checkbox"/> T4b <input type="checkbox"/> T1 <input type="checkbox"/> T4 <input type="checkbox"/> TX	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"/> N1b <input type="checkbox"/> N2a <input type="checkbox"/> N1 <input type="checkbox"/> N1c <input type="checkbox"/> N2b <input type="checkbox"/> N1a <input type="checkbox"/> N2 <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).
42	Pathologic spread: Distant metastases (pM)	<input type="checkbox"/> M0 <input type="checkbox"/> M1a <input type="checkbox"/> M1c <input type="checkbox"/> M1 <input type="checkbox"/> M1b	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 IIIB <input type="checkbox"/> Stage I <input type="checkbox"/> Stage IIIC <input type="checkbox"/> Stage IIA <input type="checkbox"/> Stage IVA <input type="checkbox"/> Stage IIB <input type="checkbox"/> Stage IVB <input type="checkbox"/> Stage IIC <input type="checkbox"/> Stage IVC <input type="checkbox"/> Stage IIIA	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"/> G4-Undifferentiated <input type="checkbox"/> GB-Borderline histologic grade <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"/> Liver <input type="checkbox"/> Peritoneum <input type="checkbox"/> Lung <input type="checkbox"/> Lymph nodes <input type="checkbox"/> Brain <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>



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
<b>Prognostic/Predictive/Lifestyle Features for Tumor Prognosis or Responsiveness to Treatment</b>				
48	Preoperative CEA level	_____	2752	Provide the carcinoembryonic antigen (CEA) level (ng/ml) prior to resection of the tumor submitted to HCMI.
49	Microsatellite instability identified?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	3123142	Indicate whether microsatellite instability was present in more than 33% of loci tested. <b>Note: If not performed, skip to Question 52.</b>
50	Number of loci tested	<input type="checkbox"/> 1 <input type="checkbox"/> 8 <input type="checkbox"/> 15 <input type="checkbox"/> 2 <input type="checkbox"/> 9 <input type="checkbox"/> 16 <input type="checkbox"/> 3 <input type="checkbox"/> 10 <input type="checkbox"/> 17 <input type="checkbox"/> 4 <input type="checkbox"/> 11 <input type="checkbox"/> 18 <input type="checkbox"/> 5 <input type="checkbox"/> 12 <input type="checkbox"/> 19 <input type="checkbox"/> 6 <input type="checkbox"/> 13 <input type="checkbox"/> 20 <input type="checkbox"/> 7 <input type="checkbox"/> 14	3107127	Provide the number of loci tested to detect microsatellite instability.
51	Number of abnormal loci	<input type="checkbox"/> 1 <input type="checkbox"/> 8 <input type="checkbox"/> 15 <input type="checkbox"/> 2 <input type="checkbox"/> 9 <input type="checkbox"/> 16 <input type="checkbox"/> 3 <input type="checkbox"/> 10 <input type="checkbox"/> 17 <input type="checkbox"/> 4 <input type="checkbox"/> 11 <input type="checkbox"/> 18 <input type="checkbox"/> 5 <input type="checkbox"/> 12 <input type="checkbox"/> 19 <input type="checkbox"/> 6 <input type="checkbox"/> 13 <input type="checkbox"/> 20 <input type="checkbox"/> 7 <input type="checkbox"/> 14	3107129	Provide the number of loci found to be abnormal during testing to detect microsatellite instability.
52	Mismatch repair status	<input type="checkbox"/> Evidence of MMR mutation by sequencing <input type="checkbox"/> Evidence of MMR protein loss by IHC <input type="checkbox"/> MMR loss evidence hypermutation phenotype (>10 mutations/Mb) <input type="checkbox"/> No evidence of MMR alteration	6002208	Indicate the mismatch repair (MMR) status and the mechanism by which it was determined.
53	Was MLH1 IHC performed?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	6062411	Indicate whether MLH1 expression was assessed by immunohistochemistry (IHC). <b>Note: If not performed, skip to Question 55.</b>
54	MLH1 expression by IHC	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Equivocal	6063668	Indicate the status of MLH1 protein expression as determined by immunohistochemistry (IHC).
55	MLH1 promoter methylation status	<input type="checkbox"/> MLH1 promoter hypermethylation present <input type="checkbox"/> MLH1 promoter hypermethylation absent <input type="checkbox"/> MLH1 promoter hypermethylation not assessed <input type="checkbox"/> Cannot be determined	6033150	Indicate the methylation status of the MLH1 promoter.
56	Was MSH2 IHC performed	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	6062412	Indicate whether MSH2 expression was assessed by immunohistochemistry (IHC). <b>Note: If not performed, skip to Question 58.</b>
57	MSH2 expression by IHC	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Equivocal	6063669	Indicate the status of MSH2 protein expression as determined by immunohistochemistry (IHC).
58	Was PMS2 IHC performed	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	6062413	Indicate whether PMS2 expression was assessed by immunohistochemistry (IHC). <b>Note: If not performed, skip to Question 60.</b>
59	PMS2 expression by IHC	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Equivocal	6063670	Indicate the status of PMS2 protein expression as determined by immunohistochemistry (IHC).
60	Was MSH6 IHC performed?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	6062414	Indicate whether MSH6 expression was assessed by immunohistochemistry (IHC). <b>Note: If not performed, skip to Question 62.</b>
61	MSH6 expression by IHC	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Equivocal	6063671	Indicate the status of MSH6 protein expression as determined by immunohistochemistry (IHC).

## Enrollment: Colon/Rectum

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62	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 65.</b>
63	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 65.</b>
64	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 64a, otherwise, skip to Question 65.</b>
64a	Other KRAS mutation(s)	_____	5525148	If the KRAS mutation identified is not provided in the previous list, specify the KRAS mutation.
65	Was BRAF mutation analysis performed?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	6061813	Indicate whether BRAF mutation analysis was performed. <b>Note: If not performed, skip to Question 68.</b>
66	Was a mutation in BRAF identified?	<input type="checkbox"/> Yes <input type="checkbox"/> No	6061809	Indicate whether a mutation in BRAF was identified through mutation analysis. <b>Note: If mutation was not identified, skip to Question 68.</b>
67	If BRAF mutation identified, which one?	<input type="checkbox"/> V600E <input type="checkbox"/> V600R <input type="checkbox"/> V600D <input type="checkbox"/> K601E <input type="checkbox"/> V600K <input type="checkbox"/> Other (specify)	6061810	Indicate the specific BRAF mutation identified. <b>Note: If the BRAF mutation is not listed, proceed to Question 67a, otherwise, skip to Question 68.</b>
67a	Other BRAF mutation	_____	6101687	If the BRAF mutation is not included in the list provided, specify the BRAF mutation identified.
68	Was BRAF IHC performed?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	6161811	Indicate whether BRAF expression was assessed by immunohistochemistry (IHC). <b>Note: If not performed, skip to Question 70.</b>
69	BRAF expression by IHC	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Equivocal	6061812	Indicate the status of BRAF protein expression as determined by immunohistochemistry (IHC).
70	Was PIK3CA mutation analysis performed?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	6063445	Indicate whether PIK3CA mutation analysis was performed. <b>Note: If not performed, skip to Question 73.</b>
71	Was a mutation in PIK3CA identified?	<input type="checkbox"/> Yes <input type="checkbox"/> No	6063524	Indicate whether a mutation in PIK3CA was identified through mutation analysis. <b>Note: If mutation was not identified, skip to Question 73.</b>
72	If PIK3CA mutation identified, in what exon?	<input type="checkbox"/> 9 <input type="checkbox"/> 20 <input type="checkbox"/> Other (specify)	6063735	Indicate the specific exon of the PIK3CA gene in which the mutation was identified. <b>Note: If the PIK3CA mutation is not listed, proceed to Question 72a, otherwise, skip to Question 73.</b>
72a	Other PIK3CA mutation	_____	6101688	If the specific exon of the PIK3CA gene mutation abnormality identified was not included in the previous list, please specify the exon.
73	Was PTEN IHC performed?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	6062415	Indicate whether PTEN expression was assessed by immunohistochemistry (IHC). <b>Note: If not performed, skip to Question 75.</b>
74	PTEN expression by IHC	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Equivocal	6063672	Indicate the status of PTEN protein expression as determined by immunohistochemistry (IHC).



## Enrollment: Colon/Rectum

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
75	Was PTEN mutation analysis performed?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	6063446	Indicate whether PTEN mutation analysis was performed. <b>Note: If not performed, skip to Question 77.</b>
76	Was a mutation in PTEN identified	<input type="checkbox"/> Yes <input type="checkbox"/> No	6063529	Indicate whether a mutation in PTEN was identified through mutation analysis.
77	History of synchronous colon/rectal tumors at time of tissue collection	<input type="checkbox"/> Yes <input type="checkbox"/> No	2185953	Indicate whether synchronous colon or rectal tumors were present time of tissue collection.
78	History of prior colon polyps	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	3107197	Indicate if the patient had a previous history of colon polyps as noted in the history/physical or previous endoscopic report(s).
79	Were colon polyps present at time of tissue collection?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	64184	Indicate if polyps were present in the colon surgically or pathologically at the time of tissue collection.
80	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 is not present, skip to Question 82.</b>
81	Venous invasion type	<input type="checkbox"/> Extramural <input type="checkbox"/> Intramural	6036344	Identify the location of vascular involvement for the tumor.
82	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.
83	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.
84	Did the patient have colorectal cancer risk factors?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	5206897	Indicate whether additional colorectal cancer risk factors are documented in the patient's medical record. <b>Note: If no colorectal cancer risk factors have been identified, skip to Question 86.</b>
85	Colorectal cancer risk factors	<input type="checkbox"/> A diet that is high in red meats and processed meats <input type="checkbox"/> Diagnosis of familial adenomatous polyposis in patient or family member <input type="checkbox"/> Obesity - weight > 20% ideal body weight <input type="checkbox"/> Previous colorectal polyps <input type="checkbox"/> Diagnosis of Lynch syndrome in patient <input type="checkbox"/> Type II diabetes <input type="checkbox"/> Other risk factors - specify	5206898	Select all of the colorectal cancer risk factors documented in the patient's medical record. <b>Note: If the colorectal cancer risk factor is not listed, proceed to Question 85a, otherwise, skip to Question 86.</b>
85a	Other colorectal cancer risk factor(s)	_____	5206899	If the patient's colorectal cancer risk factors were not included in the previous list, please specify.
86	Does the patient have a history of gastrointestinal disorder?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	3521240	Indicate whether the patient has been diagnosed with gastrointestinal disorder(s). <b>Note: If the patient was not diagnosed with gastrointestinal disorder, skip to Question 88.</b>

## Enrollment: Colon/Rectum

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
87	Gastrointestinal disorder(s) diagnosed	<input type="checkbox"/> Adenomatous polyposis coli <input type="checkbox"/> Hereditary non-polyposis colon cancer <input type="checkbox"/> Peutz-Jeghers disease <input type="checkbox"/> Ulcerative colitis <input type="checkbox"/> Crohn disease <input type="checkbox"/> Celiac disease	3211626	Select all the gastrointestinal disorder(s) with which the patient has been diagnosed.
<b>Treatment Information</b>				
88	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 96-97. Pharmaceutical therapy is addressed in Questions 89-95.</b>
89	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 90-91. Immunotherapy is addressed in Questions 92-93. Targeted therapy is addressed in Questions 94-95.</b>
90	Neoadjuvant chemotherapeutic regimen	<input type="checkbox"/> 5-fluorouracil <input type="checkbox"/> 5-FU and Leucovorin <input type="checkbox"/> Capecitabine <input type="checkbox"/> FOLFIRI <input type="checkbox"/> FOLFOX <input type="checkbox"/> Irinotecan <input type="checkbox"/> Leucovorin <input type="checkbox"/> Oxaliplatin <input type="checkbox"/> Trifluridine <input type="checkbox"/> Trifluridine and tipiracil <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 92. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 90a, otherwise, skip to Question 91.</b>
90a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapy.
91	Days to neoadjuvant chemotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with neoadjuvant chemotherapy.
92	Immunotherapy name, specify	_____	2185614	Specify the name of the Immunotherapy administered. <b>Note: If immunotherapy was not administered, skip to Question 94.</b>
93	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.

## Enrollment: Colon/Rectum

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
94	Targeted therapy	<input type="checkbox"/> Bevacizumab <input type="checkbox"/> Ramucirumab <input type="checkbox"/> Cetuximab <input type="checkbox"/> Regorafenib <input type="checkbox"/> Panitumumab <input type="checkbox"/> Ziv-aflibercept <input type="checkbox"/> PD-1 inhibitor <input type="checkbox"/> Other (specify)	6033149	Select the targeted therapy administered to the patient. <b>Note: If targeted therapy was not administered, skip to Question 96. If the targeted therapy regimen is not listed, proceed to Question 94a, otherwise, skip to Question 95.</b>
94a	Other targeted therapy	_____	4308476	If the targeted therapy is not included in the provided list, specify targeted therapy.
95	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.
96	Radiation therapy administered type	<input type="checkbox"/> 2D conventional <input type="checkbox"/> Stereotactic Body <input type="checkbox"/> 3D conformal <input type="checkbox"/> RT <input type="checkbox"/> Brachytherapy <input type="checkbox"/> Stereotactic HDR                                    Radiosurgery <input type="checkbox"/> Brachytherapy <input type="checkbox"/> WBRT 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, skip the remaining questions. If the radiation therapy is not listed, proceed to Question 96a, otherwise, skip to Question 97.</b>
96a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
97	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.