Enrollment: Breast

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Form Notes: An Enrollment Form should be completed for each HCMI case upon qualification notice from Leidos. All information provided on this form should include activity from the Date of Initial Pathologic Diagnosis to the most recent Date of Last Contact with the patient.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	☐ Initial pathologic diagnosis ☐ Sample procurement ☐ First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.
Patient Information				
4	Gender	☐ Male ☐ Female ☐ Unspecified	2200604	Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
5	Height	_____	649	Provide the patient's height, in centimeters.
6	Weight	_____	651	Provide the patient's weight, in kilograms.
7	Body mass index (BMI)	_____	2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
8	Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown ☐ Not reported	2192199	Provide the patient's race using the defined categories. **American Indian or Alaska Native:** A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment. **Asian:** A person having origins in any of the peoples of the Far East, Southeast Asia, or in the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. **Black or African American:** A person having origins in any of the black racial groups of Africa. **Native Hawaiian or other Pacific Islander:** A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island. **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
9	Ethnicity	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Not reported	2192217	Provide the patient's ethnicity using the defined categories. **Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. **Not Hispanic or Latino:** A person not meeting the definition of Hispanic or Latino.

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
10	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.
11	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. ***Note: If the patient's age is greater than 32,872 days (90 years), please enter 32,872.***
12	Year of birth	_____	2896954	Provide the year of the patient's birth. If the patient was born prior to 1928, insert the date 1928.
13	Family history of cancer	☐ Same ☐ Different ☐ None ☐ Unknown	5832923	Has a first-degree relative of the patient been diagnosed with a cancer of the same or a different type?
14	Smoking history	☐ Lifelong non-smoker (<100 cigarettes smoked in a lifetime) ☐ Current smoker (includes daily and non-daily smokers) ☐ Current reformed smoker (duration not specified) ☐ Current reformed smoker for >15 years ☐ Current reformed smoker for ≤15 years	2181650	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories.
15	Metastasis at diagnosis assessment status	☐ Metastatic ☐ Non-metastatic (confirmed) ☐ Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor. ***Note: If metastatic at diagnosis, proceed to Question 16, otherwise, skip to Question 17.***
16	Metastatic site(s) at diagnosis	☐ Bone ☐ Brain ☐ Cutaneous ☐ Liver ☐ Lung ☐ Lymph node(s) axillary ☐ Lymph node(s) non-regional ☐ Other (specify)	3029815	Indicate the site(s) of metastasis at the time of diagnosis of the primary tumor. ***Note: If the anatomic site of tumor tissue is not listed, proceed to Question 16a, otherwise, skip to Question 17.***
16a	Specify metastatic site(s)	_____	3128033	If the site of metastasis is not included on the provided list, specify the site of metastasis.
Biospecimen Information				
17	Tissue sample type(s) collected for HCMI for this case	☐ Normal tissue ☐ Primary tumor ☐ Metastatic ☐ Recurrent ☐ Other tissue	2006911	Please select all the tissue sample types submitted for HCMI with this case.
18	Number of NORMAL tissues biospecimens collected for HCMI for this case	_____	6584256	Please provide the number of normal tissue specimens obtained for HCMI for this case. ***Note: This number is expected to be 1.***
19	Number of PRIMARY cancer tissue biospecimens collected for HCMI model development for this case	_____	6584257	Please provide the number of primary tumor specimens obtained for HCMI for this case. ***Note: A single primary tumor biospecimen obtained that is portioned for both sequencing and model generation counts as 1 single primary tumor specimen. This number is expected to be 1.***

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
20	Number of METASTATIC/RECURRENT cancer tissue biospecimens collected for HCMI model development for this case	_____	6584258	Please provide the number of metastatic and/or recurrent cancer biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
21	Number of OTHER tissue biospecimens collected for HCMI model development for this case	_____	6584259	Please provide the number of pre-malignant, non-malignant, or dysplastic tissue biospecimens collected for HCMI for this case. ***Note: A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen.***
22	Total number of tissue biospecimens collected for HCMI for this case	_____	6584271	Please provide the total number of tissue biospecimens collected for HCMI for this case. ***Note: This number should be the sum of the normal, primary tumor, metastatic/ recurrent tumor, and other biospecimen counts above.***
Normal Control Information				
23	Normal tissue biospecimen ordinal	_____	6584264	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
24	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
25	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
26	Type of normal control	☐ Whole blood ☐ Buccal cells ☐ Buffy coat ☐ Lymphocytes ☐ Extracted DNA from blood ☐ Extracted DNA from saliva ☐ Extracted DNA from buccal cells ☐ Extracted DNA from normal tissue ☐ FFPE non-neoplastic tissue ☐ Non-neoplastic tissue	3081936	Indicate the type of normal control submitted for this case.
27	Anatomic site of normal tissue	☐ Left breast ☐ Right breast ☐ Lymph node(s) ☐ Other (specify) ☐ Not applicable	4132152	If non-neoplastic tissue was submitted as the normal control, select the anatomic site of the normal tissue. ***Note: If the anatomic site of normal tissue is not listed, proceed to Question 27a, otherwise, skip to Question 28.***

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
27a	Other anatomic site of normal tissue	_____	3288189	If non-neoplastic tissue, adjacent tissue, or normal tissue from another anatomic site was submitted as the normal control, provide the anatomic site of the normal tissue.
28	Distance from tumor to normal control tissue (if not blood)	☐ Adjacent (< or = 2cm) ☐ Distal (>2cm) ☐ Unknown ☐ Not applicable	3088708	Indicate the distance from the site of normal tumor collection to the primary tumor. ***Note: If normal tissue was not submitted, select 'Not applicable'.***
29	Normal tissue sample preservation method	☐ Cryopreserved ☐ OCT ☐ FFPE ☐ Snap frozen ☐ Frozen	5432521	Provide the method used to preserve the normal tissue sample collected for molecular characterization.
Primary Tumor Biospecimen Information				
30	ICD-10 code for primary tumor	☐ C50.0 ☐ C50.4 ☐ C50.8 ☐ C50.1 ☐ C50.5 ☐ C50.9 ☐ C50.2 ☐ C50.6 ☐ Other (specify) ☐ C50.3	3226287	Provide the ICD-10 code for the primary tumor as used to generate the ID3 for this subject. ***Note: If the ICD-10 code is not listed, proceed to 30a, otherwise, skip to Question 31.***
30a	Other ICD-10 code for primary tumor	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.
31	Tumor Morphology	☐ 8022/3 ☐ 8410/3 ☐ 8525/3 ☐ 8032/3 ☐ 8430/3 ☐ 8530/3 ☐ 8035/3 ☐ 8480/3 ☐ 8540/3 ☐ 8041/3 ☐ 8500/3 ☐ 8550/3 ☐ 8070/3 ☐ 8502/3 ☐ 8570/3 ☐ 8200/3 ☐ 8503/3 ☐ 8571/3 ☐ 8201/3 ☐ 8504/3 ☐ 8572/3 ☐ 8211/3 ☐ 8507/3 ☐ 8574/3 ☐ 8246/3 ☐ 8509/3 ☐ 8575/3 ☐ 8290/3 ☐ 8510/3 ☐ 8982/3 ☐ 8314/3 ☐ 8513/3 ☐ 8983/3 ☐ 8315/3 ☐ 8520/3 ☐ Other (specify)	3226275	Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor. ***Note: If the ICD-O-3 histology code of the primary tumor is not listed, proceed to Question 31a, otherwise, skip to Question 32.***
31a	Specify other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.
32	Tissue or organ of origin	☐ Breast ☐ Other (specify)	3427536	Using the patient's pathology/laboratory report, select the primary site of the disease. ***Note: If the primary site of the disease is not listed, proceed to Question 32a, otherwise skip to Question 33.***
32a	Other tissue or organ of origin	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland	3427536	If the primary site of the disease is not included on the previous list, provide the primary site of the disease.

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		☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva		
33	Histological Type	☐ Breast cancer ☐ Other (specify)	3081932	Select the surgical pathology text description of the histological tumor type. ***Note: If the histological tumor type is not listed, proceed to Question 33a, otherwise, skip to Question 34.***
33a	Other histological type	_____	3294805	If the traditional surgical pathology text description of the histological tumor type is not included on the previous list, please specify the histological type.
34	Histological subtype	☐ Infiltrating ductal carcinoma ☐ Infiltrating lobular carcinoma ☐ Mucinous carcinoma ☐ Medullary carcinoma ☐ Metaplastic ductal carcinoma ☐ Infiltrating carcinoma (NOS) ☐ Mixed histology (specify) ☐ Other (specify)	3081934	Using the patient's pathology/laboratory report, select the histological subtype of the primary tumor. ***Note: If the histological subtype is not listed, proceed to Question 34a, otherwise, skip to Question 35.***
34a	Other histological subtype	_____	3124492	If the histological subtype for the primary tumor is not included in the provided list, specify the histological subtype.
35	Prior malignancy (of the same cancer type)	☐ Yes ☐ No ☐ Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
36	Prior malignancy (other cancer type)	☐ Yes ☐ No ☐ Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.
37	AJCC cancer staging edition	☐ 1st ☐ 2nd ☐ 3rd ☐ 4th ☐ 5th ☐ 6th ☐ 7th ☐ 8th	2722309	Select the AJCC staging handbook edition used to stage the patient's primary tumor.
38	Clinical stage group	☐ Stage 0 ☐ Stage IA ☐ Stage IB ☐ Stage IIA ☐ Stage IIB ☐ Stage IIIA ☐ Stage IIIB ☐ Stage IIIC ☐ Stage IV	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).

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
39	AJCC pathologic spread: Primary tumor (pT)	☐ T0 ☐ Tis ☐ Tis (DCIS) ☐ Tis (LCIS) ☐ Tis (Paget's) ☐ T1 ☐ T1mi ☐ T1a ☐ T1b ☐ T1c ☐ T2 ☐ T3 ☐ T4 ☐ T4a ☐ T4b ☐ T4c ☐ T4d ☐ 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).
40	AJCC pathologic spread: Lymph nodes (pN)	☐ N0 ☐ N0 (i+) ☐ N0 (i-) ☐ N0 (mol+) ☐ N0 (mol-) ☐ N1 ☐ N1mi ☐ N1a ☐ N1b ☐ N1c ☐ N2 ☐ N2a ☐ N2b ☐ N3 ☐ N3a ☐ N3b ☐ N3c ☐ 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).
41	AJCC pathologic spread: Distant metastases (pM)	☐ M0 ☐ M1	3045439	Using the patient's pathology/laboratory report, select the code for the pathologic M (metastasis) as defined by the American Joint Committee on Cancer (AJCC).
42	Tumor stage (pathological)	☐ Stage 0 ☐ Stage IA ☐ Stage IB ☐ Stage IIA ☐ Stage IIB ☐ Stage IIIA ☐ Stage IIIB ☐ Stage IIIC ☐ Stage IV	3065862	Using the patient's pathology/laboratory report, in conjunction with the patient's medical record, select the stage as defined by the American Joint Committee on Cancer (AJCC).
43	Tumor grade	☐ G1-Well differentiated ☐ G2-Moderately differentiated ☐ G3-Poorly differentiated ☐ G4-Undifferentiated ☐ GB-Borderline histologic grade ☐ GX-Unknown	2785839	Using the patient's pathology/laboratory report, select the grade of the primary tumor.
44	Histopathologic grade	☐ Well differentiated ☐ Moderately differentiated ☐ Poorly differentiated ☐ Unknown	2186393	Using the patient's pathology/laboratory report, select the histopathologic grade of the primary tumor.
Prognostic/Predictive/Lifestyle Features for Primary Tumor Prognosis or Responsiveness to Treatment				
45	Menopause status	☐ Premenopausal ☐ Perimenopausal ☐ Postmenopausal ☐ Indeterminate or Unknown	2957270	Indicate the menopause status of the patient at the time of diagnosis.
46	Does the patient have bilateral malignancy (including DCIS)?	☐ Yes ☐ No ☐ Unknown	2177953	Indicate whether the patient has bilateral breast cancer (including ductal carcinoma in situ).
47	Micropapillary features	☐ Present ☐ Absent ☐ Unknown	6068784	Indicate whether micropapillary features were present in the primary tumor.
48	Did the patient receive hormonal therapy for the prevention of breast cancer?	☐ Yes ☐ No ☐ Unknown	3913290	Indicate whether the patient received hormonal therapy for the prevention of breast cancer.
49	Was Estrogen receptor (ER) IHC performed?	☐ Yes ☐ No ☐ Unknown	6062416	Indicate whether estrogen receptor (ER) expression was assessed by immunohistochemistry (IHC). ***Note: If ER IHC was not performed, skip to Question 51.***
50	ER Allred score	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8	2419219	Indicate the numeric Allred score (cell staining percentage plus intensity) for estrogen receptor.

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
51	Was Progesterone receptor (PR) IHC performed?	☐ Yes ☐ No ☐ Unknown	6062504	Indicate whether progesterone receptor (PR) expression was assessed by IHC. ***Note: If PR IHC was not performed, skip to Question 53.***
52	PR expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063673	Indicate the expression of progesterone receptor as assessed by immunohistochemistry (IHC).
53	Was HER2 IHC performed?	☐ Yes ☐ No ☐ Unknown	6063454	Indicate whether HER2 expression was assessed by immunohistochemistry (IHC). ***Note: If HER2 IHC was not performed, skip to Question 55.***
54	HER2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	2957563	Indicate the expression of HER2 as assessed by immunohistochemistry (IHC).
55	Was HER2 FISH/CISH performed?	☐ Yes ☐ No ☐ Unknown	6063447	Indicate whether HER2 was assessed by fluorescence in situ hybridization (FISH) or chromogenic in situ hybridization (CISH). ***Note: If HER2 FISH/CISH was not performed, skip to Question 57.***
56	HER2 status by FISH/CISH	☐ Amplified ☐ Not amplified ☐ Equivocal	2854089	Select the HER2 status as assessed by FISH/CISH.
57	HER2 copy number	_____	3133738	If HER2 copy number testing was performed, provide the average number of HER2 fluorescence in situ hybridization (FISH) signals for the patient's primary tumor. ***Note: If copy number analysis was not performed, skip to Question 61.***
58	Centromere 17 copy number	_____	3104295	If Centromere 17 copy number testing was performed, provide the average number of Centromere 17 fluorescence in situ hybridization (FISH) signals for the patient's primary tumor.
59	Number of cells counted for HER2 and Centromere 17 copy numbers	_____	3087902	Provide the total number of cells counted to assess HER2 and Centromere 17 copy numbers.
60	HER2/Centromere 17 signal ratio	_____	2497552	If HER2 and Centromere 17 copy number analyses were performed by FISH, provide the ratio of the outcomes of these tests.
61	Genomic test performed?	☐ Yes ☐ No ☐ Unknown	6069581	Indicate whether a genomic biomarker test (for example, Oncotype DX or MammaPrint) was performed. ***Note: If a genomic biomarker test was not performed, skip to Question 65.***
62	What genomic test was performed?	☐ Oncotype ☐ MammaPrint ☐ Other (specify)	6069582	Select the genomic test performed. ***Note: If the genomic test performed is Oncotype, proceed to Question 63. If the genomic test performed is MammaPrint, proceed to Question 64. If the genomic test performed is not listed, proceed to Questions 62a and b.***
62a	Other genomic test	_____	6069583	If the genomic test performed was not in the list, please provide the name of the test.
62b	If other genomic test was performed, provide the risk group	_____	6070422	Provide the risk group as assessed by a genomic test other than Oncotype or MammaPrint.

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
63	What is the patient's risk group according to the Oncotype recurrence score?	☐ Low ☐ Intermediate ☐ High	6069584	Indicate the risk group of the patient as determined by the Oncotype recurrence score.
64	What is the patient's risk group according to the MammaPrint test?	☐ Low ☐ High	6070421	Indicate the risk group of the patient as determined by the MammaPrint test.
Primary Tumor Sample Information				
65	Are you submitting a primary tumor tissue sample for this case?	☐ Yes ☐ No		***If yes, proceed to question 66.*** ***If submitting a metastatic/recurrent tumor sample, proceed to Question 94.***
66	Primary tumor biospecimen ordinal	_____	6584265	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number should be "1".***
67	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
68	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
69	Sample represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this primary tumor specimen represent the PRIMARY DIAGNOSIS for this Case ID3? ***Note: If no, continue to Question 70, otherwise, skip to Question 71.***
70	Specify the ICD-10 code	_____	3226287	Provide the ICD-10 code for the primary tumor used to generate the model submitted to HCMI.
71	Tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the tumor tissue sample collected for molecular characterization.
72	Anatomic Site of tumor from which Model was Derived	☐ Left breast ☐ Right breast ☐ Other (specify)	6033148	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI. ***Note: If the tissue or organ of origin is not listed, proceed to Question 72a. Otherwise, skip to Question 73.***
72a	Other anatomic site from which the tumor was obtained	_____	5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.
73	Method of cancer sample procurement	☐ Needle biopsy ☐ Lumpectomy ☐ Simple mastectomy ☐ Modified radical mastectomy ☐ Other (specify)	3103514	Provide the procedure performed to obtain the primary tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 73a, otherwise, skip to Question 74.***
73a	Specify the other method of tumor sample procurement	_____	2006730	Specify the procedure performed to obtain the primary tumor tissue, if not included in the previous list.
74	Number of days from index date to date of tumor sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the tumor tissue submitted for HCMI.
75	Tumor tissue type	☐ Primary ☐ Additional Primary ☐ NOS	3288124	Provide the primary tumor tissue type for this sample.

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Primary Tumor Model Information				
76	Primary model biospecimen ordinal	_____	6594596	Please provide a number to identify which biospecimen this is in the sequence. ***Note: This number is expected to be "1".***
77	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
78	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
79	Model represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this MODEL represent the PRIMARY DIAGNOSIS for this Case ID3?
80	Model's primary tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the PRIMARY TUMOR TISSUE from which this model is derived.
81	Model's primary tumor biospecimen ordinal	_____	6584265	Enter the biospecimen ordinal of the PRIMARY TUMOR TISSUE from which this model is derived.
Treatment Information				
82	History of neoadjuvant treatment	☐ No ☐ Yes; radiation prior to resection ☐ Yes; pharmaceutical treatment prior to resection ☐ Yes; both radiation and pharmaceutical treatment prior to resection ☐ Unknown	3382737	Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment. ***Note: Pharmaceutical therapy is addressed in Questions 83-91. Radiation therapy is addressed in Questions 92-93.***
83	Neoadjuvant chemotherapy type	☐ Cytotoxic chemotherapy ☐ Hormonal ☐ Immunotherapy (cellular and immune checkpoint) ☐ Targeted therapy (small molecule inhibitors and targeted antibodies) ☐ Not applicable	5832928	Select all neoadjuvant chemotherapy types that were administered to the patient. ***Note: Cytotoxic chemotherapy is addressed in Questions 84-85. Hormone therapy is addressed in Questions 86-87. Immunotherapy is addressed in Questions 88-89. Targeted therapy is addressed in Questions 90-91.***
84	Neoadjuvant chemotherapeutic regimen	☐ 5-fluorouracil ☐ Albumin-bound paclitaxel ☐ Capecitabine ☐ Carboplatin ☐ Cisplatin ☐ Docetaxel ☐ Epirubicin ☐ Eribulin ☐ Gemcitabine ☐ Ixabepilone ☐ Lapatinib ☐ Liposomal Doxorubicin ☐ Methotrexate ☐ Mitoxantrone ☐ Neratinib ☐ Paclitaxel ☐ T-DM1 ☐ Trastuzumab ☐ Vinorelbine ☐ Other (specify) ☐ Chemotherapy not given	2853313	Select all chemotherapeutics used for neoadjuvant therapy. ***Note: If neoadjuvant chemotherapy was not given, skip to Question 86. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 84a, otherwise, skip to Question 85.***
84a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapies administered.
85	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.

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
86	Hormone therapy	☐ Anastrazole ☐ Exemestane ☐ Fulvestrant ☐ Letrozole ☐ LHRH agonist ☐ Tamoxifen ☐ Toremifene ☐ Other (specify)	6326083	Select the hormone therapy administered to the patient. ***Note: If the hormone therapy regimen is not listed, proceed to Question 86a, otherwise, skip to Question 87.***
86a	Other hormone therapy	_____	2405358	If the hormone therapy is not included in the provided list, specify hormone therapy administered.
87	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.
88	Immunotherapy	_____	2953828	If the immunotherapy is not included in the provided list, specify immunotherapy administered.
89	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
90	Targeted Therapy	☐ Ado-trastuzumab emtansine ☐ Everolimus ☐ Lapatinib ☐ Palbociclib ☐ Pertuzumab ☐ Ribociclib ☐ Trastuzumab ☐ Other (specify)	6326084	Select the targeted therapy administered to the patient. ***Note: If the targeted therapy regimen is not listed, proceed to Question 90a, otherwise, skip to Question 91.***
90a	Specify targeted therapy	_____	4308476	Provide the name of the targeted therapy administered to the patient.
91	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.
92	Radiation therapy administered type	☐ 2D conventional ☐ 3D conformal ☐ Brachytherapy HDR ☐ Brachytherapy LDR ☐ IMRT ☐ Proton Beam ☐ Stereotactic Body RT ☐ Stereotactic Radiosurgery ☐ WBRT ☐ Other (specify) ☐ Unspecified ☐ Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. ***Note: If radiation therapy was not administered, proceed to Question 94. If the radiation therapy is not listed, proceed to Question 92a, otherwise, skip to Question 93.***
92a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
93	Days to radiation treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with radiation therapy.
Metastatic/Recurrent Tumor Biospecimen Information				
94	Are you submitting a metastatic/recurrent tumor tissue sample?	☐ Yes ☐ No		Indicate whether a metastatic/recurrent tumor biospecimen was collected for this ID3 case. ***Note: If yes, proceed to Question 95. If submitting an OTHER tissue sample, proceed to Question 182.***
95	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1", the second should be number "2", etc.***
96	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.

Enrollment: Breast

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
97	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
98	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
99	Number of days from index date to date of diagnosis of metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic/recurrent disease.
100	Method of metastatic/ recurrent cancer sample procurement	☐ Needle biopsy ☐ Lumpectomy ☐ Simple mastectomy ☐ Modified radical mastectomy ☐ Other (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 100a, otherwise, skip to Question 101.***
100a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
101	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
102	Metastatic/recurrent site	☐ Left breast ☐ Right breast ☐ Bone ☐ Brain ☐ Cutaneous ☐ Liver ☐ Lung ☐ Lymph node(s) axillary ☐ Lymph node(s) non-regional ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 102a, otherwise, skip to Question 103.***
102a	Other metastatic/ recurrent site	_____	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
103	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
104	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
105	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
106	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.
107	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.

Enrollment: Breast

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
108	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
109	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
110	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
111	Tumor grade	☐ G1-Well differentiated ☐ G2-Moderately differentiated ☐ G3-Poorly differentiated ☐ G4-Undifferentiated ☐ GB-Borderline histologic grade ☐ GX-Unknown	2785839	Using the patient's pathology/laboratory report, select the grade of the primary tumor.
112	Histopathologic grade	☐ Well differentiated ☐ Moderately differentiated ☐ Poorly differentiated ☐ Unknown	2186393	Using the patient's pathology/laboratory report, select the histopathologic grade of the primary tumor.
Prognostic/Predictive/Lifestyle Features for Metastatic/Recurrent Tumor Prognosis or Responsiveness to Treatment				
113	Menopause status	☐ Premenopausal ☐ Perimenopausal ☐ Postmenopausal ☐ Indeterminate or Unknown	2957270	Indicate the menopause status of the patient at the time of diagnosis.
114	Does the patient have bilateral malignancy (including DCIS)?	☐ Yes ☐ No ☐ Unknown	2177953	Indicate whether the patient has bilateral breast cancer (including ductal carcinoma in situ).
115	Micropapillary features	☐ Present ☐ Absent ☐ Unknown	6068784	Indicate whether micropapillary features were present in the primary tumor.
116	Did the patient receive hormonal therapy for the prevention of breast cancer?	☐ Yes ☐ No ☐ Unknown	3913290	Indicate whether the patient received hormonal therapy for the prevention of breast cancer.
117	Was Estrogen receptor (ER) IHC performed?	☐ Yes ☐ No ☐ Unknown	6062416	Indicate whether estrogen receptor (ER) expression was assessed by immunohistochemistry (IHC). ***Note: If ER IHC was not performed, skip to Question 119.***
118	ER Allred score	☐ 0 ☐ 3 ☐ 6 ☐ 1 ☐ 4 ☐ 7 ☐ 2 ☐ 5 ☐ 8	2419219	Indicate the numeric Allred score (cell staining percentage plus intensity) for estrogen receptor.
119	Was Progesterone receptor (PR) IHC performed?	☐ Yes ☐ No ☐ Unknown	6062504	Indicate whether progesterone receptor (PR) expression was assessed by IHC. ***Note: If PR IHC was not performed, skip to Question 121.***
120	PR expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063673	Indicate the expression of progesterone receptor as assessed by immunohistochemistry (IHC).
121	Was HER2 IHC performed?	☐ Yes ☐ No ☐ Unknown	6063454	Indicate whether HER2 expression was assessed by immunohistochemistry (IHC). ***Note: If HER2 IHC was not performed, skip to Question 123.***
122	HER2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	2957563	Indicate the expression of HER2 as assessed by immunohistochemistry (IHC).

Enrollment: Breast

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
123	Was HER2 FISH/CISH performed?	☐ Yes ☐ No ☐ Unknown	6063447	Indicate whether HER2 was assessed by fluorescence in situ hybridization (FISH) or chromogenic in situ hybridization (CISH). ***Note: If HER2 FISH/CISH was not performed, skip to Question 125.***
124	HER2 status by FISH/CISH	☐ Amplified ☐ Not amplified ☐ Equivocal	2854089	Select the HER2 status as assessed by FISH/CISH.
125	HER2 copy number	_____	3133738	If HER2 copy number testing was performed, provide the average number of HER2 fluorescence in situ hybridization (FISH) signals for the patient's primary tumor. ***Note: If copy number analysis was not performed, skip to Question 129.***
126	Centromere 17 copy number	_____	3104295	If Centromere 17 copy number testing was performed, provide the average number of Centromere 17 fluorescence in situ hybridization (FISH) signals for the patient's primary tumor.
127	Number of cells counted for HER2 and Centromere 17 copy numbers	_____	3087902	Provide the total number of cells counted to assess HER2 and Centromere 17 copy numbers.
128	HER2/Centromere 17 signal ratio	_____	2497552	If HER2 and Centromere 17 copy number analyses were performed by FISH, provide the ratio of the outcomes of these tests.
129	Genomic test performed?	☐ Yes ☐ No ☐ Unknown	6069581	Indicate whether a genomic biomarker test (for example, Oncotype DX or MammaPrint) was performed. ***Note: If a genomic biomarker test was not performed, skip to Question 133.***
130	What genomic test was performed?	☐ Oncotype ☐ MammaPrint ☐ Other (specify)	6069582	Select the genomic test performed. ***Note: If the genomic test performed is Oncotype, proceed to Question 131. If the genomic test performed is MammaPrint, proceed to Question 132. If the genomic test performed is not listed, proceed to Questions 130a and b.***
130a	Other genomic test	_____	6069583	If the genomic test performed was not in the list, please provide the name of the test.
130b	If other genomic test was performed, provide the risk group	_____	6070422	Provide the risk group as assessed by a genomic test other than Oncotype or MammaPrint.
131	What is the patient's risk group according to the Oncotype recurrence score?	☐ Low ☐ Intermediate ☐ High	6069584	Indicate the risk group of the patient as determined by the Oncotype recurrence score.
132	What is the patient's risk group according to the MammaPrint test?	☐ Low ☐ High	6070421	Indicate the risk group of the patient as determined by the MammaPrint test.
Additional Metastatic/Recurrent Tumor Biospecimen Information (if applicable)				
133	Are you submitting an additional metastatic/ recurrent tumor tissue sample?	☐ Yes ☐ No		A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen. ***Note: If yes, proceed to Question 134, otherwise, skip to Question 172.***

Enrollment: Breast

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
134	Metastatic/recurrent tissue biospecimen ordinal	_____	6584266	Please provide a number to identify which biospecimen this is in the sequence. The first biospecimen should be number "1," the second should be number "2," etc.
135	CMDC tissue ID	_____	6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
136	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
137	Metastatic/ recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
138	Number of days from index date to date of diagnosis of additional metastasis/ recurrence	_____	6132218	Provide the number of days from the index date to the date of diagnosis of additional metastatic/recurrent disease.
139	Method of metastatic/ recurrent cancer sample procurement	☐ Needle biopsy ☐ Lumpectomy ☐ Simple mastectomy ☐ Modified radical mastectomy ☐ Other (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. ***Note: If the method of procurement is not listed, proceed to Question 139a, otherwise, skip to Question 140.***
139a	Other method of cancer sample procurement	_____	6587390	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
140	Number of days from index date to date of metastatic/ recurrent sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the metastatic/recurrent tumor tissue submitted for HCMI.
141	Metastatic/ recurrent site	☐ Left breast ☐ Right breast ☐ Bone ☐ Brain ☐ Cutaneous ☐ Liver ☐ Lung ☐ Lymph node(s) axillary ☐ Lymph node(s) non-regional ☐ Other (specify)	6587394	Select the site from which the metastatic/recurrent tissue used to develop the model was derived. ***Note: If the metastatic/recurrent site is not listed, proceed to Question 141a, otherwise, skip to Question 142.***
141a	Other metastatic/ recurrent site	_____	6587395	If not included in the previous list, specify the site from which the metastatic/recurrent tissue used to develop the model was derived.
142	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
143	ICD-10 code	_____	3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
144	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the metastatic/recurrent tumor used to generate the model submitted to HCMI.
145	Maintenance and/or consolidation therapy administered prior to collection of metastatic/ recurrent tissue	_____	6119066	Provide the name(s) of the maintenance and/or consolidation therapy administered to the patient prior to the collection of the metastatic/recurrent tissue used to develop the model.

Enrollment: Breast

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
146	Days to start of maintenance and/or consolidation therapy from index date	_____	5102411	Provide the number of days from the index date to the date maintenance and/or consolidation therapy started.
147	Days to last known administration date of maintenance and/or consolidation therapy from index date	_____	5102431	Provide the number of days from the index date to the last known date of maintenance and/or consolidation therapy.
148	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
149	Disease status	☐ No evidence of disease ☐ Progressive disease ☐ Stable disease ☐ Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
Prognostic/Predictive/Lifestyle Features for Additional Metastatic/Recurrent Tumor Prognosis or Responsiveness to Treatment				
150	Tumor grade	☐ G1-Well differentiated ☐ G2-Moderately differentiated ☐ G3-Poorly differentiated ☐ G4-Undifferentiated ☐ GB-Borderline histologic grade ☐ GX-Unknown	2785839	Using the patient's pathology/laboratory report, select the grade of the primary tumor.
151	Histopathologic grade	☐ Well differentiated ☐ Moderately differentiated ☐ Poorly differentiated ☐ Unknown	2186393	Using the patient's pathology/laboratory report, select the histopathologic grade of the primary tumor.
152	Menopause status	☐ Premenopausal ☐ Perimenopausal ☐ Postmenopausal ☐ Indeterminate or Unknown	2957270	Indicate the menopause status of the patient at the time of diagnosis.
153	Does the patient have bilateral malignancy (including DCIS)?	☐ Yes ☐ No ☐ Unknown	2177953	Indicate whether the patient has bilateral breast cancer (including ductal carcinoma in situ).
154	Micropapillary features	☐ Present ☐ Absent ☐ Unknown	6068784	Indicate whether micropapillary features were present in the primary tumor.
155	Did the patient receive hormonal therapy for the prevention of breast cancer?	☐ Yes ☐ No ☐ Unknown	3913290	Indicate whether the patient received hormonal therapy for the prevention of breast cancer.
156	Was Estrogen receptor (ER) IHC performed?	☐ Yes ☐ No ☐ Unknown	6062416	Indicate whether estrogen receptor (ER) expression was assessed by immunohistochemistry (IHC). ***Note: If ER IHC was not performed, skip to Question 158.***
157	ER Allred score	☐ 0 ☐ 3 ☐ 6 ☐ 1 ☐ 4 ☐ 7 ☐ 2 ☐ 5 ☐ 8	2419219	Indicate the numeric Allred score (cell staining percentage plus intensity) for estrogen receptor.
158	Was Progesterone receptor (PR) IHC performed?	☐ Yes ☐ No ☐ Unknown	6062504	Indicate whether progesterone receptor (PR) expression was assessed by IHC. ***Note: If PR IHC was not performed, skip to Question 160.***
159	PR expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063673	Indicate the expression of progesterone receptor as assessed by immunohistochemistry (IHC).
160	Was HER2 IHC performed?	☐ Yes ☐ No ☐ Unknown	6063454	Indicate whether HER2 expression was assessed by immunohistochemistry (IHC). ***Note: If HER2 IHC was not performed, skip to Question 162.***

Enrollment: Breast

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
161	HER2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	2957563	Indicate the expression of HER2 as assessed by immunohistochemistry (IHC).
162	Was HER2 FISH/CISH performed?	☐ Yes ☐ No ☐ Unknown	6063447	Indicate whether HER2 was assessed by fluorescence in situ hybridization (FISH) or chromogenic in situ hybridization (CISH). ***Note: If HER2 FISH/CISH was not performed, skip to Question 164.***
163	HER2 status by FISH/CISH	☐ Amplified ☐ Not amplified ☐ Equivocal	2854089	Select the HER2 status as assessed by FISH/CISH.
164	HER2 copy number	_____	3133738	If HER2 copy number testing was performed, provide the average number of HER2 fluorescence in situ hybridization (FISH) signals for the patient's primary tumor. ***Note: If copy number analysis was not performed, skip to Question 168.***
165	Centromere 17 copy number	_____	3104295	If Centromere 17 copy number testing was performed, provide the average number of Centromere 17 fluorescence in situ hybridization (FISH) signals for the patient's primary tumor.
166	Number of cells counted for HER2 and Centromere 17 copy numbers	_____	3087902	Provide the total number of cells counted to assess HER2 and Centromere 17 copy numbers.
167	HER2/Centromere 17 signal ratio	_____	2497552	If HER2 and Centromere 17 copy number analyses were performed by FISH, provide the ratio of the outcomes of these tests.
168	Genomic test performed?	☐ Yes ☐ No ☐ Unknown	6069581	Indicate whether a genomic biomarker test (for example, Oncotype DX or MammaPrint) was performed. ***Note: If a genomic biomarker test was not performed, skip to Question 172.***
169	What genomic test was performed?	☐ Oncotype ☐ MammaPrint ☐ Other (specify)	6069582	Select the genomic test performed. ***Note: If the genomic test performed is Oncotype, proceed to Question 170. If the genomic test performed is MammaPrint, proceed to Question 171. If the genomic test performed is not listed, proceed to Questions 169a and b.***
169a	Other genomic test	_____	6069583	If the genomic test performed was not in the list, please provide the name of the test.
169b	If other genomic test was performed, provide the risk group	_____	6070422	Provide the risk group as assessed by a genomic test other than Oncotype or MammaPrint.
170	What is the patient's risk group according to the Oncotype recurrence score?	☐ Low ☐ Intermediate ☐ High	6069584	Indicate the risk group of the patient as determined by the Oncotype recurrence score.
171	What is the patient's risk group according to the MammaPrint test?	☐ Low ☐ High	6070421	Indicate the risk group of the patient as determined by the MammaPrint test.
Metastatic/Recurrent Tumor Model Information				
172	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***

Enrollment: Breast

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
173	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
174	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
175	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
176	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Additional Metastatic/Recurrent Biospecimen Tumor Model Information (if applicable)				
177	METASTATIC/ RECURRENT model biospecimen ordinal	_____	6594587	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
178	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
179	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
180	Model's METASTATIC/ RECURRENT tumor tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue from which this model is derived.
181	Model's METASTATIC/ RECURRENT tumor tissue biospecimen ordinal	_____	6584266	Enter the biospecimen ordinal of the METASTATIC/RECURRENT tissue from which this model is derived.
Other Biospecimen Information				
182	Are you submitting an OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an OTHER tissue sample (e.g. pre-malignant, non-malignant, or dysplastic tissue, etc.) was collected for HCMI for this case. ***Note: If yes, proceed to Question 183.***
183	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
184	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
185	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
186	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.

Enrollment: Breast

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
187	Other method of cancer sample procurement	☐ Needle biopsy ☐ Lumpectomy ☐ Simple mastectomy ☐ Modified radical mastectomy ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 187a, otherwise, skip to Question 188.***
187a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
188	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
189	Tissue type	☐ Non-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 189a, otherwise, skip to Question 190.***
189a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
190	Anatomic site of OTHER tissue	☐ Left breast ☐ Right breast ☐ Bone ☐ Brain ☐ Liver ☐ Lung ☐ Lymph node ☐ Skin ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 190a, otherwise, skip to Question 191.***
190a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.
191	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
192	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Additional OTHER biospecimen Information (if applicable)				
193	Are you submitting an additional OTHER tissue sample?	☐ Yes ☐ No		Indicate whether an additional OTHER tissue sample (pre-malignant, non-malignant, or dysplastic tissue, etc.) is being submitted for HCMI for this case. ***Note: If yes, proceed to Question 194, otherwise, skip to Question 204.***
194	OTHER tissue biospecimen ordinal	_____	6584267	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
195	CMDC sample ID	_____	6586035	Please provide the CMDC sample ID for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
196	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
197	OTHER tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.

Enrollment: Breast

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
198	Other method of cancer sample procurement	☐ Needle biopsy ☐ Lumpectomy ☐ Simple mastectomy ☐ Modified radical mastectomy ☐ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. ***Note: If the method of procurement is not listed, proceed to Question 198a, otherwise, skip to Question 199.***
198a	Specify method of OTHER tissue sample procurement	_____	6587399	Specify the procedure performed to obtain the OTHER tissue.
199	Number of days from index date to date of OTHER sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
200	Tissue type	☐ Non-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type. ***Note: If the OTHER tissue type is not listed, proceed to Question 200a, otherwise, skip to Question 201.***
200a	Specify tissue type	_____	64785	Specify the OTHER tissue type if not in the provided list.
201	Anatomic site of OTHER tissue	☐ Left breast ☐ Right breast ☐ Bone ☐ Brain ☐ Liver ☐ Lung ☐ Lymph node ☐ Skin ☐ Other (specify)	6696813	Select the site from which the OTHER tissue used to develop the model was derived. ***Note: If the OTHER tissue site is not listed, proceed to Question 201a, otherwise, skip to Question 202.***
201a	Specify anatomic site of OTHER tissue	_____	6584916	Specify the site of OTHER tissue, if not in the previous list.
202	ICD-10 code	_____	3226287	Provide the ICD-10 code for the OTHER tissue used to generate the model submitted to HCMI.
203	ICD-O-3 histology code	_____	3226275	Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Other Tissue Model Information				
204	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***
205	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
206	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
207	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
208	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.
Additional Other Tissue Model Information (if applicable)				
209	OTHER tissue model biospecimen ordinal	_____	6594590	Please provide a number to identify which biospecimen this is in the sequence. ***Note: The first biospecimen should be number "1," the second should be number "2," etc.***

Enrollment: Breast

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
210	CMDC model ID	_____	6586036	Please provide the CMDC model ID for this sample as it will appear on tubes and the Sample Submission Form transmitted to the BPC.
211	BPC submitter ID (if available)	_____	6584919	Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
212	Model's OTHER tissue CMDC sample ID	_____	6586035	Enter the CMDC Sample ID of the OTHER tissue from which this model is derived.
213	Model's OTHER tissue biospecimen ordinal	_____	6584267	Enter the biospecimen ordinal of the OTHER tissue from which this model is derived.