

## 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	<input type="checkbox"/> Initial pathologic diagnosis <input type="checkbox"/> Sample procurement <input type="checkbox"/> First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.
<b>Normal Control Information</b>				
4	Type of normal control	<input type="checkbox"/> Whole blood <input type="checkbox"/> Buccal cells <input type="checkbox"/> Buffy coat <input type="checkbox"/> Lymphocytes <input type="checkbox"/> Extracted DNA from blood <input type="checkbox"/> Extracted DNA from saliva <input type="checkbox"/> Extracted DNA from buccal cells <input type="checkbox"/> Extracted DNA from normal tissue <input type="checkbox"/> FFPE non-neoplastic tissue <input type="checkbox"/> Non-neoplastic tissue	3081936	Indicate the type of normal control submitted for this case.
5	Anatomic site of normal tissue	<input type="checkbox"/> Left breast <input type="checkbox"/> Right breast <input type="checkbox"/> Lymph node(s) <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"/> Left breast <input type="checkbox"/> Right breast <input type="checkbox"/> Bone <input type="checkbox"/> Brain <input type="checkbox"/> Liver <input type="checkbox"/> Lung <input type="checkbox"/> Lymph node <input type="checkbox"/> Skin <input type="checkbox"/> Other (specify)	4214629	Indicate the anatomic site of the tumor tissue used to generate the model for the HCMI. <b>Note: If the anatomic site of tumor tissue is not listed, proceed to Question 8a, otherwise, skip to Question 9.</b>
8a	Other anatomic site	_____	5946219	If the anatomic site for the tumor submitted to HCMI is not included on the provided list, specify the anatomic site.

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9	Method of cancer sample procurement	<input type="checkbox"/> Needle biopsy <input type="checkbox"/> Lumpectomy <input type="checkbox"/> Simple mastectomy <input type="checkbox"/> Modified radical mastectomy <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"/> C50.0 <input type="checkbox"/> C77.9 <input type="checkbox"/> C50.1 <input type="checkbox"/> C78.0 <input type="checkbox"/> C50.2 <input type="checkbox"/> C78.7 <input type="checkbox"/> C50.3 <input type="checkbox"/> C79.3 <input type="checkbox"/> C50.4 <input type="checkbox"/> C79.5 <input type="checkbox"/> C50.5 <input type="checkbox"/> C79.7 <input type="checkbox"/> C50.6 <input type="checkbox"/> C79.8 <input type="checkbox"/> C50.8 <input type="checkbox"/> Other (specify) <input type="checkbox"/> C50.9	3226287	Provide the ICD-10 code for the tumor used to generate the model submitted to HCMI. <b>Note: If the ICD-10 code is not listed, proceed to Question 11a, otherwise, skip to Question 12.</b>
11a	Other ICD-10 code	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.
12	Tumor tissue type	<input type="checkbox"/> Premalignant <input type="checkbox"/> Primary <input type="checkbox"/> Recurrent <input type="checkbox"/> Metastatic <input type="checkbox"/> Additional primary <input type="checkbox"/> NOS	3288124	Provide the tumor tissue type for the biospecimen used to produce the model for the HCMI. <b>Note: If 'Metastatic' is selected, continue to answer through Question 20. If the tissue is not 'Metastatic', skip to Question 21.</b>
<b>Metastatic Model Information</b> (only complete Questions 13-20 if 'Metastatic' was selected in Question 12)				
13	Age at diagnosis of metastasis	_____	6032752	Provide the age (in days) of the patient when diagnosed with metastatic disease. If the patient's age is greater than 32,507 days (89 years), please enter 32,507.
14	Number of days from index date to date of diagnosis of metastasis	_____	6132218	Provide the number of days from the index date to the date of diagnosis of metastatic disease.
15	Metastatic site	<input type="checkbox"/> Bone <input type="checkbox"/> Brain <input type="checkbox"/> Cutaneous <input type="checkbox"/> Liver <input type="checkbox"/> Lung <input type="checkbox"/> Lymph node(s) axillary <input type="checkbox"/> Lymph node(s) non-regional <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 treatment.
19	Is the patient still receiving treatment?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy treatment.
20	Disease status	<input type="checkbox"/> No evidence of disease <input type="checkbox"/> Progressive disease <input type="checkbox"/> Stable disease <input type="checkbox"/> Unknown	2188290	Provide the disease status following maintenance and/or consolidation therapy.
<b>Patient Information</b>				
21	Gender	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unspecified	2200604	Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
22	Height	_____	649	Provide the patient's height, in centimeters.
23	Weight	_____	651	Provide the patient's weight, in kilograms.
24	Body mass index (BMI)	_____	2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
25	Race	<input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian or other Pacific Islander <input type="checkbox"/> White <input type="checkbox"/> Unknown <input type="checkbox"/> Not allowed to collect	2192199	Provide the patient's race using the defined categories. <b>American Indian or Alaska Native:</b> A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment. <b>Asian:</b> A person having origins in any of the peoples of the Far East, Southeast Asia, or in the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Phillipine Islands, Thailand, and Vietnam. <b>Black or African American:</b> A person having origins in any of the black racial groups of Africa. <b>Native Hawaiian or other Pacific Islander:</b> A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island. <b>White:</b> A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

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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"/> 8022/3 <input type="checkbox"/> 8410/3 <input type="checkbox"/> 8525/3 <input type="checkbox"/> 8032/3 <input type="checkbox"/> 8430/3 <input type="checkbox"/> 8530/3 <input type="checkbox"/> 8035/3 <input type="checkbox"/> 8480/3 <input type="checkbox"/> 8540/3 <input type="checkbox"/> 8041/3 <input type="checkbox"/> 8500/3 <input type="checkbox"/> 8550/3 <input type="checkbox"/> 8070/3 <input type="checkbox"/> 8502/3 <input type="checkbox"/> 8570/3 <input type="checkbox"/> 8200/3 <input type="checkbox"/> 8503/3 <input type="checkbox"/> 8571/3 <input type="checkbox"/> 8201/3 <input type="checkbox"/> 8504/3 <input type="checkbox"/> 8572/3 <input type="checkbox"/> 8211/3 <input type="checkbox"/> 8507/3 <input type="checkbox"/> 8574/3 <input type="checkbox"/> 8246/3 <input type="checkbox"/> 8509/3 <input type="checkbox"/> 8575/3 <input type="checkbox"/> 8290/3 <input type="checkbox"/> 8510/3 <input type="checkbox"/> 8982/3 <input type="checkbox"/> 8314/3 <input type="checkbox"/> 8513/3 <input type="checkbox"/> 8983/3 <input type="checkbox"/> 8315/3 <input type="checkbox"/> 8520/3 <input type="checkbox"/> Other (specify)	3226275	Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor. <b>Note: If the morphology is not listed, proceed to Question 32a, otherwise, skip to Question 33.</b>
32a	Other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.
33	Tissue or organ of origin	<input type="checkbox"/> Breast <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"/> Breast 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"/> Infiltrating ductal carcinoma <input type="checkbox"/> Infiltrating lobular carcinoma <input type="checkbox"/> Mucinous carcinoma <input type="checkbox"/> Medullary carcinoma <input type="checkbox"/> Metaplastic ductal carcinoma <input type="checkbox"/> Infiltrating carcinoma (NOS) <input type="checkbox"/> Mixed histology (specify) <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>
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.

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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 IIIA <input type="checkbox"/> Stage IA <input type="checkbox"/> Stage IIIB <input type="checkbox"/> Stage IB <input type="checkbox"/> Stage IIIC <input type="checkbox"/> Stage IIA <input type="checkbox"/> Stage IV <input type="checkbox"/> Stage IIB	3440332	Using the patient's pathology/laboratory report, select the clinical stage group of the primary tumor as defined by the American Joint Committee on Cancer (AJCC).
40	Pathologic spread: Primary tumor (pT)	<input type="checkbox"/> T0 <input type="checkbox"/> T1 <input type="checkbox"/> T4 <input type="checkbox"/> Tis <input type="checkbox"/> T1mi <input type="checkbox"/> T4a <input type="checkbox"/> Tis (DCIS) <input type="checkbox"/> T1a <input type="checkbox"/> T4b <input type="checkbox"/> Tis (LCIS) <input type="checkbox"/> T1b <input type="checkbox"/> T4c <input type="checkbox"/> Tis (Paget's) <input type="checkbox"/> T1c <input type="checkbox"/> T4d <input type="checkbox"/> T2 <input type="checkbox"/> TX <input type="checkbox"/> T3	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"/> N1 <input type="checkbox"/> N2b <input type="checkbox"/> N0 (i+) <input type="checkbox"/> N1mi <input type="checkbox"/> N3 <input type="checkbox"/> N0 (i-) <input type="checkbox"/> N1a <input type="checkbox"/> N3a <input type="checkbox"/> N0 (mol+) <input type="checkbox"/> N1b <input type="checkbox"/> N3b <input type="checkbox"/> N0 (mol-) <input type="checkbox"/> N1c <input type="checkbox"/> N3c <input type="checkbox"/> N2 <input type="checkbox"/> NX <input type="checkbox"/> N2a	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"/> 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).
43	Tumor stage (pathological)	<input type="checkbox"/> Stage 0 <input type="checkbox"/> Stage IIIA <input type="checkbox"/> Stage IA <input type="checkbox"/> Stage IIIB <input type="checkbox"/> Stage IB <input type="checkbox"/> Stage IIIC <input type="checkbox"/> Stage IIA <input type="checkbox"/> Stage IV <input type="checkbox"/> Stage IIB	3203222	Using the patient's pathology/laboratory report, in conjunction with the patient's medical record, select the stage as defined by the American Joint Committee on Cancer (AJCC).
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"/> Bone <input type="checkbox"/> Lymph node(s) axillary <input type="checkbox"/> Brain <input type="checkbox"/> Lymph node(s) non-regional <input type="checkbox"/> Cutaneous <input type="checkbox"/> Unknown <input type="checkbox"/> Liver <input type="checkbox"/> Other (specify) <input type="checkbox"/> Lung	3029815	Indicate all the site(s) of metastasis at the time of diagnosis of the primary tumor. <b>Note: If the metastatic site(s) is not listed, proceed to Question 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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<b>Prognostic/Predictive/Lifestyle Features for Tumor Prognosis or Responsiveness to Treatment</b>				
48	Menopause status	<input type="checkbox"/> Premenopausal <input type="checkbox"/> Perimenopausal <input type="checkbox"/> Postmenopausal <input type="checkbox"/> Indeterminate or Unknown	2957270	Indicate the menopause status of the patient at the time of diagnosis.
49	Does the patient have bilateral malignancy (including DCIS)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	2177953	Indicate whether the patient has bilateral breast cancer (including ductal carcinoma in situ).
50	Micropapillary features	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Unknown	6068784	Indicate whether micropapillary features were present in the primary tumor.
51	Did the patient receive hormonal therapy for the prevention of breast cancer?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	3913290	Indicate whether the patient received hormonal therapy for the prevention of breast cancer.
52	Was Estrogen receptor (ER) IHC performed?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	6062416	Indicate whether estrogen receptor (ER) expression was assessed by immunohistochemistry (IHC). <b>Note: If ER IHC was not performed, skip to Question 54.</b>
53	ER Allred score	<input type="checkbox"/> 0 <input type="checkbox"/> 3 <input type="checkbox"/> 6 <input type="checkbox"/> 1 <input type="checkbox"/> 4 <input type="checkbox"/> 7 <input type="checkbox"/> 2 <input type="checkbox"/> 5 <input type="checkbox"/> 8	2419219	Indicate the numeric Allred score (cell staining percentage plus intensity) for estrogen receptor.
54	Was Progesterone receptor (PR) IHC performed?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	6062504	Indicate whether progesterone receptor (PR) expression was assessed by IHC. <b>Note: If PR IHC was not performed, skip to Question 56.</b>
55	PR expression by IHC	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Equivocal	6063673	Indicate the expression of progesterone receptor as assessed by immunohistochemistry (IHC).
56	Was HER2 IHC performed?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	6063454	Indicate whether HER2 expression was assessed by immunohistochemistry (IHC). <b>Note: If HER2 IHC was not performed, skip to Question 58.</b>
57	HER2 expression by IHC	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Equivocal	2957563	Indicate the expression of HER2 as assessed by immunohistochemistry (IHC).
58	Was HER2 FISH/CISH performed?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	6063447	Indicate whether HER2 was assessed by fluorescence in situ hybridization (FISH) or chromogenic in situ hybridization (CISH). <b>Note: If HER2 FISH/CISH was not performed, skip to Question 60.</b>
59	HER2 status by FISH/CISH	<input type="checkbox"/> Amplified <input type="checkbox"/> Not amplified <input type="checkbox"/> Equivocal	2854089	Select the HER2 status as assessed by FISH/CISH.
60	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. <b>Note: If copy number analysis was not performed, skip to Question 64.</b>
61	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.

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62	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.
63	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.
64	Genomic test performed?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	6069581	Indicate whether a genomic biomarker test (for example, Oncotype DX or MammaPrint) was performed. <b>Note: If a genomic biomarker test was not performed, skip to Question 68.</b>
65	What genomic test was performed?	<input type="checkbox"/> Oncotype <input type="checkbox"/> MammaPrint <input type="checkbox"/> Other (specify)	6069582	Select the genomic test performed. <b>Note: If the genomic test performed is Oncotype, proceed to Question 66. If the genomic test performed is MammaPrint, proceed to Question 67. If the genomic test performed is not listed, proceed to Questions 65a and b.</b>
65a	Other genomic test	_____	6069583	If the genomic test performed was not in the list, please provide the name of the test.
65b	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.
66	What is the patient's risk group according to the Oncotype recurrence score?	<input type="checkbox"/> Low <input type="checkbox"/> Intermediate <input type="checkbox"/> High	6069584	Indicate the risk group of the patient as determined by the Oncotype recurrence score.
67	What is the patient's risk group according to the MammaPrint test?	<input type="checkbox"/> Low <input type="checkbox"/> High	6070421	Indicate the risk group of the patient as determined by the MammaPrint test.
<b>Treatment Information</b>				
68	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 78-79. Pharmaceutical therapy is addressed in Questions 69-77.</b>
69	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 70-71. Hormonal therapy is addressed in Questions 72-73. Immunotherapy is addressed in Questions 74-75. Targeted therapy is addressed in Questions 76-77.</b>



## 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
70	Neoadjuvant chemotherapeutic regimen	<input type="checkbox"/> 5-fluorouracil <input type="checkbox"/> Albumin-bound paclitaxel <input type="checkbox"/> Capecitabine <input type="checkbox"/> Carboplatin <input type="checkbox"/> Cisplatin <input type="checkbox"/> Docetaxel <input type="checkbox"/> Epirubicin <input type="checkbox"/> Eribulin <input type="checkbox"/> Gemcitabine <input type="checkbox"/> Ixabepilone <input type="checkbox"/> Lapatinib <input type="checkbox"/> Liposomal Doxorubicin <input type="checkbox"/> Methotrexate <input type="checkbox"/> Mitoxantrone <input type="checkbox"/> Neratinib <input type="checkbox"/> Paclitaxel <input type="checkbox"/> T-DM1 <input type="checkbox"/> Trastuzumab <input type="checkbox"/> Vinorelbine <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 72. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 70a, otherwise, skip to Question 71.</b>
70a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapy.
71	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.
72	Hormone therapy	<input type="checkbox"/> Anastrozole <input type="checkbox"/> CDK4/6 inhibitor <input type="checkbox"/> Exemestane <input type="checkbox"/> Fulvestrant <input type="checkbox"/> Letrozole <input type="checkbox"/> LHRH agonist <input type="checkbox"/> Tamoxifen <input type="checkbox"/> Toremifene <input type="checkbox"/> Other (specify)	2582817	Select the hormone therapy administered to the patient. <b>Note: If the hormone therapy regimen is not listed, proceed to Question 72a, otherwise, skip to Question 73.</b>
72a	Other hormone therapy	_____	2405358	If the hormone therapy is not included in the provided list, specify hormone therapy.
73	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.
74	Immunotherapy	_____	2953828	Specify the name of the Immunotherapy administered. <b>Note: If immunotherapy was not administered, skip to Question 76.</b>
75	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
76	Targeted therapy	<input type="checkbox"/> Ado-trastuzumab emtansine <input type="checkbox"/> Everolimus <input type="checkbox"/> Lapatinib <input type="checkbox"/> Palbociclib <input type="checkbox"/> Pertuzumab <input type="checkbox"/> Ribociclib <input type="checkbox"/> Trastuzumab <input type="checkbox"/> Other (specify)	6068764	Select the targeted therapy administered to the patient. <b>Note: If targeted therapy was not administered, skip to Question 78. If the targeted therapy regimen is not listed, proceed to Question 76a, otherwise, skip to Question 77.</b>
76a	Other targeted therapy	_____	4308476	If the targeted therapy is not included in the provided list, specify targeted therapy.

## 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
77	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.
78	Radiation therapy administered type	<input type="checkbox"/> 2D conventional <input type="checkbox"/> 3D conformal <input type="checkbox"/> Brachytherapy HDR <input type="checkbox"/> Brachytherapy LDR <input type="checkbox"/> IMRT <input type="checkbox"/> Proton Beam <input type="checkbox"/> Stereotactic Body RT <input type="checkbox"/> Stereotactic Radiosurgery <input type="checkbox"/> WBRT <input type="checkbox"/> Other (specify) <input type="checkbox"/> Unspecified <input type="checkbox"/> Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. <b>Note: If radiation therapy was not administered, skip the remaining questions. If the radiation therapy is not listed, proceed to Question 78a, otherwise, skip to Question 79.</b>
78a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
79	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.