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### **Enrollment: Breast**

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Fissue 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		6154722	Select the reference date used to calculate time intervals (e.g. days to
		☐ Initial pathologic diagnosis		treatment). Date of initial pathologic
		☐ Sample procurement		diagnosis is the HCMI standard and should
		☐ First patient visit		be used unless it is unavailable. If an
				alternative index date is used, indicate it here and use it for all interval calculations.
Patient Inf	formation			
4	Gender		2200604	Provide the patient's gender using the
		Male		defined categories. Identification of
		☐ Female		gender is based upon self-report and may
		☐ Unspecified		come from a form, questionnaire, interview, etc.
5	Height		649	Provide the patient's height, in
6	Moight		651	centimeters.
0	Weight		021	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
8	Race		2192199	index (BMI).  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.
		☐ American Indian or Alaska Native		Asian: A person having origins in any of the
		☐ Asian		peoples of the Far East, Southeast Asia, or in
		☐ Black or African American		the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia,
		☐ Native Hawaiian or other Pacific Islander		Pakistan, the Philippine Islands, Thailand, and
		White		Vietnam.  Black or African American: A person having
		☐ Unknown ☐ Not reported		origins in any of the black racial groups of
		- Not reported		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		2192217	Provide the patient's ethnicity using the
				defined categories.
		☐ Hispanic or Latino		Hispanic or Latino: A person of Mexican, Puerto Rican, Cuban, Central or South
		☐ Not Hispanic or Latino		American or other Spanish culture or origin,
		☐ Unknown		regardless of race.
		☐ Not reported		<b>Not Hispanic or Latino:</b> A person not meeting the definition of Hispanic or Latino.
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Tissue Source Site (TSS) Name:	HCMI Identifier (ID3):	<b>100</b>
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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	<ul> <li>□ Lifelong non-smoker (&lt;100 cigarettes smoked in a lifetime)</li> <li>□ Current smoker (includes daily and non-daily smokers)</li> <li>□ Current reformed smoker (duration not specified)</li> <li>□ Current reformed smoker for &gt;15 years</li> <li>□ Current reformed smoker for ≤15 years</li> </ul>	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	<ul> <li>☐ Metastatic</li> <li>☐ Non-metastatic (confirmed)</li> <li>☐ Non-metastatic (unconfirmed)</li> </ul>	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.
Biospecim	en Information			metastasis.
17	Tissue sample type(s) collected for HCMI for this case	<ul> <li>□ Normal tissue</li> <li>□ Primary tumor</li> <li>□ Metastatic</li> <li>□ Recurrent</li> <li>□ Other tissue</li> </ul>	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.

## **Enrollment: Breast**

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



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 Co	ntrol 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	<ul> <li>□ Whole blood</li> <li>□ Buccal cells</li> <li>□ Buffy coat</li> <li>□ Lymphocytes</li> <li>□ Extracted DNA from blood</li> <li>□ Extracted DNA from saliva</li> <li>□ Extracted DNA from buccal cells</li> <li>□ Extracted DNA from normal tissue</li> <li>□ FFPE non-neoplastic tissue</li> <li>□ Non-neoplastic tissue</li> </ul>	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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	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
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 Tu	mor Biospecimen Informatio	on	•	
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)	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 □ 8550/3 □ 8041/3 □ 8500/3 □ 8570/3 □ 8070/3 □ 8502/3 □ 8571/3 □ 8200/3 □ 8503/3 □ 8571/3 □ 8201/3 □ 8504/3 □ 8572/3 □ 8211/3 □ 8504/3 □ 8574/3 □ 8246/3 □ 8509/3 □ 8575/3 □ 8290/3 □ 8510/3 □ 8982/3 □ 8314/3 □ 8510/3 □ 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       □ Other ill-defined         □ Accessory       sites         sinus       □ Ovary         □ Adrenal gland       □ Palate         □ Anus       □ Pancreas         □ Appendix       □ Penis         □ Bladder       □ Peripheral nerves         □ Bone       and autonomic         □ Breast       nervous system of         □ Connective,       trunk         subcutaneous       □ Peritoneum         and other       □ Pharynx         soft tissues       □ Pituitary gland         □ Esophagus       □ 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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Tissue Source Site (TSS) Name: Completed By:	Enrollment: Breast  HCMI Identifier (ID3):  Completion Date (MM/DD/YYYY):			
	☐ Gallbladder☐ Gum☐ Head, face or	☐ Rectosigmoid junction ☐ Renal pelvis ☐ Retroperitoneum		

		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			3081932	Select the surgical pathology text
		☐ Breast cancer☐ Other (specify)			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 duct ☐ Infiltrating lobu ☐ Mucinous carcii ☐ Medullary carci ☐ Metaplastic duc ☐ Infiltrating carci ☐ Mixed histology ☐ Other (specify)	llar carcinoma noma noma ctal carcinoma inoma (NOS)	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	☐ 1 <sup>st</sup> ☐ 2 <sup>nd</sup> ☐ 3 <sup>rd</sup> ☐ 4 <sup>th</sup>	☐ 5 <sup>th</sup> ☐ 6 <sup>th</sup> ☐ 7 <sup>th</sup> ☐ 8 <sup>th</sup>	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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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
39	AJCC pathologic spread: Primary tumor (pT)	□ T0       □ T1       □ T4         □ Tis       □ T1mi       □ T4a         □ Tis (DCIS)       □ T1b       □ T4b         □ Tis (LCIS)       □ T1c       □ T4c         □ Tis       □ T2       □ TX         (Paget's)       □ T3       □ 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)	N1	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 IIIC ☐ Stage IIB ☐ 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	<ul> <li>□ Well differentiated</li> <li>□ Moderately differentiated</li> <li>□ Poorly differentiated</li> <li>□ Unknown</li> </ul>	2186393	Using the patient's pathology/laboratory report, select the histopathologic grade of the primary tumor.
Prognostic	/Predictive/Lifestyle Feature	es for Primary Tumor Prognosis or Responsiven	ess to Treati	nent
45	Menopause status	<ul> <li>□ Premenopausal</li> <li>□ Perimenopausal</li> <li>□ Postmenopausal</li> <li>□ Indeterminate or Unknown</li> </ul>	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 □ 3 □ 6 □ 1 □ 4 □ 7 □ 2 □ 5 □ 8	2419219	Indicate the numeric Allred score (cell staining percentage plus intensity) for estrogen receptor.

Tissue Source Site (TSS) Name:

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
51	Was Progesterone	☐ Yes	6062504	Indicate whether progesterone receptor
	receptor (PR) IHC	□ No		(PR) expression was assessed by IHC.
	performed?	☐ Unknown		Note: If PR IHC was not performed, skip to Question 53.
52	PR expression by IHC	☐ Positive	6063673	Indicate the expression of progesterone
	, , ,	☐ Negative		receptor as assessed by
		☐ Equivocal		immunohistochemistry (IHC).
53	Was HER2 IHC	☐ Yes	6063454	Indicate whether HER2 expression was
	performed?	□ No		assessed by immunohistochemistry (IHC).
		☐ Unknown		Note: If HER2 IHC was not performed, skip to Question 55.
54	HER2 expression by IHC	☐ Positive	2957563	Indicate the expression of HER2 as
34	TIERZ expression by life	☐ Negative	2557505	assessed by immunohistochemistry (IHC).
		☐ Equivocal		, (,
55	Was HER2 FISH/CISH		6063447	Indicate whether HER2 was assessed by
	performed?	☐ Yes		fluorescence in situ hybridization (FISH) or
		□ No		chromogenic in situ hybridization (CISH).
		☐ Unknown		Note: If HER2 FISH/CISH was not performed, skip to Question 57.
56	HER2 status by FISH/CISH	☐ Amplified	2854089	Select the HER2 status as assessed by
30	TIERZ Status by Tistiy cisti	□ Not amplified	2034003	FISH/CISH.
		☐ Equivocal		
		·		
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		3104295	If Centromere 17 copy number testing
	number			was performed, provide the average
				number of Centromere 17 fluorescence in
				situ hybridization (FISH) signals for the
	Number of cells counted		2007002	patient's primary tumor.  Provide the total number of cells counted
59	for HER2 and Centromere		3087902	to assess HER2 and Centromere 17 copy
	17 copy numbers			numbers.
60	HER2/Centromere 17		2497552	If HER2 and Centromere 17 copy number
	signal ratio			analyses were performed by FISH, provide
				the ratio of the outcomes of these tests.
61	Genomic test performed?		6069581	Indicate whether a genomic biomarker
		□ Yes		test (for example, Oncotype DX or
		□ No		MammaPrint) was performed. Note: If a
		☐ Unknown		genomic biomarker test was not performed, skip to Question 65.
				3
62	What genomic test was		6069582	Select the genomic test performed.
	performed?			Note: If the genomic test performed is
		☐ Oncotype		Oncotype, proceed to Question 63. If the genomic test performed is MammaPrint,
		☐ MammaPrint		proceed to Question 64. If the genomic test
		☐ Other (specify)		performed is not listed, proceed to Questions
				62a and b.
62a	Other genomic test		6069583	If the genomic test performed was not in
OZd	Other genomic test		0003383	the list, please provide the name of the
				test.
62b	If other genomic test was		6070422	Provide the risk group as assessed by a
	performed, provide the			genomic test other than Oncotype or
	risk group			MammaPrint.

Tissue Source Site (TSS) Name: \_\_\_\_\_

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
63	What is the patient's risk	□ Low	6069584	Indicate the risk group of the patient as
	group according to the	☐ Intermediate		determined by the Oncotype recurrence
	Oncotype recurrence	☐ High		score.
	score?	1 11611		
64	What is the patient's risk	□ Low	6070421	Indicate the risk group of the patient as
	group according to the	☐ High		determined by the MammaPrint test.
	MammaPrint test?	0		
	mor Sample Information	☐ Yes		If yes, proceed to question 66.
65	Are you submitting a primary tumor tissue	□ No		If submitting a metastatic/recurrent tumor
	sample for this case?	L NO		sample, proceed to Question 94.
66	Primary tumor		6584265	Please provide a number to identify which
00	biospecimen ordinal		0301203	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		6584919	Please provide the BPC-generated ID for
	available)			this sample as it will appear on the
		<del></del>		Sample Submission Form transmitted to
69	Sample represents		6584730	the BPC.  Does this primary tumor specimen
03	primary diagnosis?	□ Yes	0364730	represent the PRIMARY DIAGNOSIS for
	primary diagnosis:	□ No		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	☐ Cryopreserved	5432521	Provide the method used to preserve the
	preservation method	☐ FFPE		tumor tissue sample collected for
		☐ Frozen ☐ OCT		molecular characterization.
		☐ Snap frozen		
72	Anatomic Site of tumor	☐ Left breast	6033148	Select the anatomic site of the tumor
, =	from which Model was	☐ Right breast	00001.0	tissue sample used to generate the model
	Derived	☐ Other (specify)		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		5946219	If not provided in the previous list,
	which the tumor was			provide the anatomic site of the tumor
	obtained	<del></del>		tissue sample used to generate the model
73	Method of cancer sample	☐ Needle biopsy	3103514	for HCMI.  Provide the procedure performed to
/3	procurement	☐ Lumpectomy	3103314	obtain the primary tumor tissue. <i>Note: If</i>
	p. oour criterit	☐ Simple mastectomy		the method of procurement is not listed,
		☐ Modified radical mastectomy		proceed to Question 73a, otherwise, skip to
		☐ Other (specify)		Question 74.
73a	Specify the other method		2006730	Specify the procedure performed to
	of tumor sample			obtain the primary tumor tissue, if not
	procurement			included in the previous list.
74	Number of days from		3288495	Provide the number of days from the
	index date to date of			index date to the date of the procedure
	tumor sample	- <del></del>		that produced the tumor tissue submitted
75	procurement Tumor tissue tune		2200124	for HCMI.
75	Tumor tissue type	☐ Primary	3288124	Provide the primary tumor tissue type for this sample.
		☐ Additional Primary		τιιο σαπιριε.
		□ NOS		
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### **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
-	ımor Model Information	Data Littly Options	CDLID	Instruction Text
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.
	Information			
82	History of neoadjuvant treatment	<ul> <li>No</li> <li>Yes; radiation prior to resection</li> <li>Yes; pharmaceutical treatment prior to resection</li> <li>Yes; both radiation and pharmaceutical treatment prior to resection</li> <li>Unknown</li> </ul>	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	<ul> <li>□ Cytotoxic chemotherapy</li> <li>□ Hormonal</li> <li>□ Immunotherapy (cellular and immune checkpoint)</li> <li>□ Targeted therapy (small molecule inhibitors and targeted antibodies)</li> <li>□ Not applicable</li> </ul>	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 □ Liposomal □ Albumin-bound □ paclitaxel □ Methotrexate □ Capecitabine □ Mitoxantrone □ Carboplatin □ Paclitaxel □ Docetaxel □ T-DM1 □ Epirubicin □ Trastuzumab □ Eribulin □ Vinorelbine □ Gemcitabine □ Other (specify) □ Ixabepilone □ Chemotherapy □ Lapatinib □ Vinotelbine □ Chemotherapy	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.
	/Recurrent Tumor Biospecin	nen Information		1	
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.

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Question	Question Text	Data Entry Options		CDE ID	Instruction Text
97	BPC submitter ID (if available)	Data Entily Options		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 samp 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 mastector □ Modified radical r □ Other (specify)		6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. Note: If the method of procurement 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, spec 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 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.

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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	<ul><li>□ No evidence of disease</li><li>□ Progressive disease</li><li>□ Stable disease</li><li>□ Unknown</li></ul>	2188290	Provide the disease status following maintenance and/or consolidation therapy.
111	Tumor grade	<ul> <li>□ G1-Well differentiated</li> <li>□ G2-Moderately differentiated</li> <li>□ G3-Poorly differentiated</li> <li>□ G4-Undifferentiated</li> <li>□ GB-Borderline histologic grade</li> <li>□ GX-Unknown</li> </ul>	2785839	Using the patient's pathology/laboratory report, select the grade of the primary tumor.
112	Histopathologic grade	<ul><li>☐ Well differentiated</li><li>☐ Moderately differentiated</li><li>☐ Poorly differentiated</li><li>☐ Unknown</li></ul>	2186393	Using the patient's pathology/laboratory report, select the histopathologic grade of the primary tumor.
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113	Menopause status	<ul><li>□ Premenopausal</li><li>□ Perimenopausal</li><li>□ Postmenopausal</li><li>□ Indeterminate or Unknown</li></ul>	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	<ul><li>□ Positive</li><li>□ Negative</li><li>□ Equivocal</li></ul>	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 ☐ Fauivocal	2957563	Indicate the expression of HER2 as assessed by immunohistochemistry (IHC).

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
123	Was HER2 FISH/CISH		6063447	Indicate whether HER2 was assessed by
	performed?	☐ Yes		fluorescence in situ hybridization (FISH) or
		□ No		chromogenic in situ hybridization (CISH).
		☐ Unknown		Note: If HER2 FISH/CISH was not performed,
				skip to Question 125.
124	HER2 status by FISH/CISH	☐ Amplified	2854089	Select the HER2 status as assessed by
		□ Not amplified		FISH/CISH.
		☐ Equivocal		
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		3104295	If Centromere 17 copy number testing
120	number		3104233	was performed, provide the average
	Hamber			number of Centromere 17 fluorescence in
				situ hybridization (FISH) signals for the
				patient's primary tumor.
127	Number of cells counted		3087902	Provide the total number of cells counted
	for HER2 and Centromere			to assess HER2 and Centromere 17 copy
	17 copy numbers			numbers.
128	HER2/Centromere 17		2497552	If HER2 and Centromere 17 copy number
	signal ratio			analyses were performed by FISH, provide
				the ratio of the outcomes of these tests.
129	Genomic test performed?		6069581	Indicate whether a genomic biomarker
	•	☐ Yes		test (for example, Oncotype DX or
		□ No		MammaPrint) was performed. Note: If a
		☐ Unknown		genomic biomarker test was not performed,
				skip to Question 133.
130	What genomic test was	_	6069582	Select the genomic test performed.
	performed?	☐ Oncotype		Note: If the genomic test performed is Oncotype, proceed to Question 131. If the genomic test
		☐ MammaPrint		performed is MammaPrint, proceed to Question
		☐ Other (specify)		132. If the genomic test performed is not listed,
			5050500	proceed to Questions 130a and b.
130a	Other genomic test		6069583	If the genomic test performed was not in
		<del></del>		the list, please provide the name of the
4201-	If all an area are in the attention		6070422	test.
130b	If other genomic test was		6070422	Provide the risk group as assessed by a
	performed, provide the	<del></del>		genomic test other than Oncotype or
131	risk group What is the patient's risk		6069584	MammaPrint. Indicate the risk group of the patient as
131	group according to the	□ Low	0005364	determined by the Oncotype recurrence
	Oncotype recurrence	☐ Intermediate		score.
	score?	☐ High		36016.
132	What is the patient's risk	_	6070421	Indicate the risk group of the patient as
	group according to the	Low		determined by the MammaPrint test.
	MammaPrint test?	☐ High		
Additional		r Biospecimen Information (if applicable)		•
133	Are you submitting an	17 FF 1		A biospecimen obtained from a single site at
	additional metastatic/			a single timepoint in progression that is
	recurrent tumor tissue			portioned for both sequencing and model
	sample?			generation counts as 1 single tumor
		□ Yes		specimen. A biospecimen obtained from
		□ No		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.

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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		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	<ul> <li>□ Needle biopsy</li> <li>□ Lumpectomy</li> <li>□ Simple mastectomy</li> <li>□ Modified radical maste</li> <li>□ Other (specify)</li> </ul>	ectomy	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	<ul><li>□ Local</li><li>□ Regional</li><li>□ Distant</li><li>□ Not applicable</li></ul>		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.

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
146	Days to start of		5102411	Provide the number of days from the
	maintenance and/or			index date to the date maintenance
	consolidation therapy			and/or consolidation therapy started.
	from index date			
147	Days to last known		5102431	Provide the number of days from the
	administration date of			index date to the last known date of
	maintenance and/or			maintenance and/or consolidation
	consolidation therapy			therapy.
_	from index date			
148	Is the patient still	☐ Yes	6379568	Indicate whether the patient is still
	receiving treatment?	□ No		undergoing maintenance and/or
1.10	<u> </u>	Unknown	2400200	consolidation therapy.
149	Disease status	□ No evidence of disease	2188290	Provide the disease status following
		☐ Progressive disease☐ Stable disease		maintenance and/or consolidation
		☐ Unknown		therapy.
Duoanostis	/Duadiativa /l ifaatula Faatuus		. Droamosis or	Post and in contract to Traction and
150		s for Additional Metastatic/Recurrent Tumor  G1-Well differentiated	2785839	Using the patient's pathology/laboratory
130	Tumor grade	☐ G2-Moderately differentiated	2/65839	report, select the grade of the primary
		☐ G3-Poorly differentiated		tumor.
		☐ G3-Footify differentiated		tumor.
		☐ GB-Borderline histologic grade		
		GX-Unknown		
151	Histopathologic grade	☐ Well differentiated	2186393	Using the patient's pathology/laboratory
		☐ Moderately differentiated		report, select the histopathologic grade of
		☐ Poorly differentiated		the primary tumor.
		☐ Unknown		,
152	Menopause status	☐ Premenopausal	2957270	Indicate the menopause status of the
	•	☐ Perimenopausal		patient at the time of diagnosis.
		☐ Postmenopausal		
		☐ Indeterminate or Unknown		
153	Does the patient have	☐ Yes	2177953	Indicate whether the patient has bilateral
	bilateral malignancy	□ No		breast cancer (including ductal carcinoma
	(including DCIS)?	☐ Unknown		in situ).
154	Micropapillary features	☐ Present	6068784	Indicate whether micropapillary features
		☐ Absent		were present in the primary tumor.
		☐ Unknown		
155	Did the patient receive	□ Yes	3913290	Indicate whether the patient received
	hormonal therapy for the	□ No		hormonal therapy for the prevention of
	prevention of breast	☐ Unknown		breast cancer.
450	cancer?		6062446	Lodina and a shirt of a shirt
156	Was Estrogen receptor	☐ Yes	6062416	Indicate whether estrogen receptor (ER)
	(ER) IHC performed?	□ No		expression was assessed by immunohistochemistry (IHC). <i>Note: If ER</i>
		☐ Unknown		IHC was not performed, skip to Question 158.
157	ER Allred score	□ 0 □ 3 □ 6	2419219	Indicate the numeric Allred score (cell
13,	Zit / till Cd 3col C		2-13213	staining percentage plus intensity) for
				estrogen receptor.
158	Was Progesterone		6062504	Indicate whether progesterone receptor
	receptor (PR) IHC	☐ Yes		(PR) expression was assessed by IHC.
	performed?	□ No □ Unknown		Note: If PR IHC was not performed, skip to
	•			Question 160.
159	PR expression by IHC	□ Positive	6063673	Indicate the expression of progesterone
		☐ Negative		receptor as assessed by
		☐ Equivocal		immunohistochemistry (IHC).
160	Was HER2 IHC	□ Yes	6063454	Indicate whether HER2 expression was
	performed?	□ No		assessed by immunohistochemistry (IHC).
		☐ Unknown		Note: If HER2 IHC was not performed, skip to
				Question 162.

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
161	HER2 expression by IHC	☐ Positive	2957563	Indicate the expression of HER2 as
		☐ Negative		assessed by immunohistochemistry (IHC).
		☐ Equivocal		
162	Was HER2 FISH/CISH	_	6063447	Indicate whether HER2 was assessed by
	performed?	Yes		fluorescence in situ hybridization (FISH) or
		□ No		chromogenic in situ hybridization (CISH).
		☐ Unknown		Note: If HER2 FISH/CISH was not performed,
163	HER2 status by FISH/CISH	☐ Amplified	2854089	skip to Question 164. Select the HER2 status as assessed by
105	TIERZ Status by Horry close	☐ Not amplified	2034003	FISH/CISH.
		☐ Equivocal		11311, 613111
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		3104295	If Centromere 17 copy number testing
	number			was performed, provide the average
				number of Centromere 17 fluorescence in
				situ hybridization (FISH) signals for the
166	Number of cells counted		3087902	patient's primary tumor.  Provide the total number of cells counted
100	for HER2 and Centromere		3007302	to assess HER2 and Centromere 17 copy
	17 copy numbers			numbers.
167	HER2/Centromere 17		2497552	If HER2 and Centromere 17 copy number
	signal ratio			analyses were performed by FISH, provide
				the ratio of the outcomes of these tests.
168	Genomic test performed?		6069581	Indicate whether a genomic biomarker
		☐ Yes		test (for example, Oncotype DX or
		□ No		MammaPrint) was performed. <i>Note: If a</i>
		☐ Unknown		genomic biomarker test was not performed,
169	What ganamis tast was		6069582	skip to Question 172.
109	What genomic test was performed?		0009382	Select the genomic test performed.  Note: If the genomic test performed is
	periorinea	☐ Oncotype		Oncotype, proceed to Question 170. If the
		☐ MammaPrint		genomic test performed is MammaPrint,
		☐ Other (specify)		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
1034	other genomic test		0005505	the list, please provide the name of the
				test.
169b	If other genomic test was		6070422	Provide the risk group as assessed by a
	performed, provide the			genomic test other than Oncotype or
	risk group			MammaPrint.
170	What is the patient's risk	□ Low	6069584	Indicate the risk group of the patient as
	group according to the	☐ Intermediate		determined by the Oncotype recurrence
	Oncotype recurrence	☐ High		score.
4	score?		6076161	
171	What is the patient's risk	П. г.	6070421	Indicate the risk group of the patient as
	group according to the MammaPrint test?	□ Low		determined by the MammaPrint test.
	iviaiiiiiariiiit test?	│ □ High		
Metastatio	 :/Recurrent Tumor Model Inj	l formation	<u> </u>	<u> </u>
172	METASTATIC/		6594587	Please provide a number to identify
·	RECURRENT model			which biospecimen this is in the
	biospecimen ordinal			sequence. Note: The first biospecimen should
	,			be number "1," the second should be number
				"2," etc.

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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			6584919	Please provide the BPC-generated ID
	available)				for this sample as it will appear on the
					Sample Submission Form transmitted
					to the BPC.
175	Model's METASTATIC/			6586035	Enter the CMDC Sample ID of the
	RECURRENT tumor tissue				METASTATIC/RECURRENT tissue from
	CMDC sample ID				which this model is derived.
176	Model's METASTATIC/			6584266	Enter the biospecimen ordinal
	RECURRENT tumor tissue				of the METASTATIC/RECURRENT tissue
	biospecimen ordinal				from which this model is derived.
	Metastatic/Recurrent Biosp	ecimen Tumor Model In	formation (if applicable)		
177	METASTATIC/			6594587	Please provide a number to identify
	RECURRENT model				which biospecimen this is in the
	biospecimen ordinal				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
170	CIVIDE MODELLE			0300030	this sample as it will appear on tubes and
					the Sample Submission Form transmitted
					to the BPC.
179	BPC submitter ID (if			6584919	Please provide the BPC-generated ID for
	available)				this sample as it will appear on the
	a variable,				Sample Submission Form transmitted to
					the BPC.
180	Model's METASTATIC/			6586035	Enter the CMDC Sample ID of the
	RECURRENT tumor tissue				METASTATIC/RECURRENT tissue from
	CMDC sample ID				which this model is derived.
181	Model's METASTATIC/			6584266	Enter the biospecimen ordinal of the
	RECURRENT tumor tissue				METASTATIC/RECURRENT tissue from
	biospecimen ordinal				which this model is derived.
	pecimen Information	1			
182	Are you submitting an				Indicate whether an OTHER tissue sample
	OTHER tissue sample?	☐ Yes			(e.g. pre-malignant, non-malignant, or
		□ No			dysplastic tissue, etc.) was collected for
					HCMI for this case. <i>Note: If yes, proceed to</i>
183	OTHER tissue			6584267	Question 183.  Please provide a number to identify
103				0304207	which biospecimen this is in the
	biospecimen ordinal				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
	i				transmitted to the BPC.
				CE04040	Please provide the BPC-generated ID for
185	BPC submitter ID (if			6584919	
185	BPC submitter ID (if available)			6584919	this sample as it will appear on the
185	<u> </u>			6584919	
185	<u> </u>			6584919	this sample as it will appear on the
185	<u> </u>	☐ Cryopreserved	Пост	5432521	this sample as it will appear on the Sample Submission Form transmitted to the BPC.  Provide the method used to preserve the
	available)	☐ Cryopreserved☐ FFPE	□ OCT □ Snap frozen		this sample as it will appear on the Sample Submission Form transmitted to the BPC.

Completed By: \_\_\_\_

Tissue Source Site (TSS) Name: \_\_\_\_\_

Elli Ollillelli. Dieast	A PORT TO
HCMI Identifier (ID3):	(A)
Completion Date (MM/DD/YYYY):	ant

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Other (specify)	Question	Question Text	Data Entry Options		CDE ID	Instruction Text
Simple mastectomy   Mote: If the method of procurement is not flisted, proceed to Question 1870, otherwish skip to Question 1870,	187				6587398	1
Modified radical mastectomy   Stated, proceed to Question 1870, otherwise, skip to Question 1870, otherwise, s		sample procurement				
Specify method of OTHER tissue sample   Dither (specify)   Sepecify the procedure performed to obtain the OTHER tissue.			-	•		
187a   Specify method of OTHER tissue sample   procurement				mastectomy		1
tissue sample procurement    188		0 10 11 1 2 ==	☐ Other (specify)		650555	·
Provide the number of days from index date to date of OTHER sample procurement	187a				6587399	
188		·				obtain the OTHER tissue.
index date to date of OTHER procedured OTHER starple procurement    189	100	•			2200405	Dravida the number of days from the
OTHER sample procurement    Sissue type	100	•			3200493	
Procurement						
Tissue type		•				1
Non-malignant   Other (specify)   Specify the OTHER tissue type is not listed proceed to Question 1980, otherwise, skip Question 190.	189	'			64784	
189a   Specify tissue type     64785   Specify the OTHER tissue type if not in provided list.   Specify the OTHER tissue type if not in provided list.   Specify the OTHER tissue type if not in provided list.   Specify anatomic site of OTHER tissue   I Lung   I L	200		☐ Non-malignant		0.70.	Note: If the OTHER tissue type is not listed,
189a   Specify thissue type			☐ Other (specify)			proceed to Question 189a, otherwise, skip to
190   Anatomic site of OTHER     Left breast     Lung   Lymph node   Skin     Liver   Skin     Other (specify)   Skin     Specify anatomic site of OTHER tissue     Liver   Other (specify)   Other (specify)   Specify anatomic site of OTHER tissue   Other (specify)   Other (specify)   Other (specify)   Specify the site of OTHER tissue, etc.   In the previous list.   Other (specify)   Oth						
190	189a	Specify tissue type			64785	Specify the OTHER tissue type if not in the
tissue   Right breast   Lungh node   Bone   Skin   Brain   Other (specify)   Elixed, proceed to Question 190a, otherwiss, skip to Question 191.  190a   Specify anatomic site of OTHER tissue   G584916   Specify the site of OTHER tissue, if not 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-0-3 histology code   3226275   Provide the ICD-0-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.  193   Are you submitting an additional OTHER tissue   Yes   Indicate whether an additional OTHER tissue sample?   Yes   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   OTHER tissue   Diospecimen ordinal   OTHER tissue   G584267   Please provide a number to identify which biospecimen this is in the sequence. Note: The first biospecimen ship is in the number "1," the second should be num "2," etc.   Indicate whether and still paper on the sample Submission Form transmitted to the BPC.  195   CMDC sample ID   G586035   Please provide the CMDC sample ID for this specimen as it will appear on the Sample Submission Form transmitted to the BPC.  196   BPC submitter ID (if available)   Cryopreserved   S432521   Provide the method used to preserve   Provide the						'
Lymph node   Bone   Brain   Lymph node   Grypererved   Brain   Brain   Disperiment   Brain   Brain   Disperiment   Brain   Brain   Disperiment   Brain   Brain   Disperiment   Brain   Brain   Brain   Brain   Disperiment   Brain	190			☐ Lung	6696813	
Bone   Brain   Cher (specify)   Skin   Brain   Cher (specify)   Specify anatomic site of OTHER tissue   Specify anatomic site of OTHER tissue   Specify anatomic site of OTHER tissue   Specify the site of OTHER tissue, if not the previous list.		tissue	_			1
Brain   Liver   Other (specify)   Security anatomic site of OTHER tissue   Isolator   OTHER tissue used to generate the model submitted to HCMI.      192						
190a Specify anatomic site of OTHER tissue						
DTHER tissue	100-	Charify anatomic -itf	⊔ Liver	, , ,	6504046	
191 ICD-10 code    3226287   Provide the ICD-10 code for the OTHEI 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 OTH tissue used to generate the model submitted to HCMI.    Additional OTHER biospecimen Information (if applicable)	190a				6584916	1
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 OTH tissue used to generate the model submitted to HCMI.  Additional OTHER biospecimen Information (if applicable)  193 Are you submitting an additional OTHER tissue sample?		OTHER USSUE	·			the previous list.
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 OTH tissue used to generate the model submitted to HCMI.  Additional OTHER biospecimen Information (if applicable)  193 Are you submitting an additional OTHER tissue sample?	101	ICD-10 code			3226287	Provide the ICD-10 code for the OTHER
Submitted to HCMI.	191	CD-10 code			3220207	
192 ICD-O-3 histology code    3226275   Provide the ICD-O-3 histology code describing the morphology of the OTH tissue used to generate the model submitted to HCMI.    Additional OTHER biospecimen Information (if applicable)     193						1
describing the morphology of the OTH tissue used to generate the model submitted to HCMI.						Submitted to Helvii.
describing the morphology of the OTH tissue used to generate the model submitted to HCMI.    Additional OTHER biospecimen Information (if applicable)	192	ICD-O-3 histology code			3226275	Provide the ICD-O-3 histology code
tissue used to generate the model submitted to HCMI.    Additional OTHER biospecimen Information (if applicable)						describing the morphology of the OTHER
Additional OTHER biospecimen Information (if applicable)  193						
193						submitted to HCMI.
additional OTHER tissue sample?  Yes  No  No  Yes  No  No  Thereful 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.  Please provide a number to identify which biospecimen this is in the sequence. Note: The first biospecimen she number "1," the second should be num "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)  BPC submitter ID (if available)  Cryopreserved  5432521  Provide the method used to preserve	Additional	OTHER biospecimen Informa	ation (if applicable)			
sample?    Yes	193					Indicate whether an additional OTHER
being submitted for HCMI for this case  Note: If yes, proceed to Question 194, otherwise, skip to Question 204.  194 OTHER tissue biospecimen ordinal  195 CMDC sample ID  196 BPC submitter ID (if available)  197 OTHER tissue sample  198 DTHER tissue sample  199 Cryopreserved  190 DTHER tissue sample						
Note: If yes, proceed to Question 194, otherwise, skip to Question 204.  194 OTHER tissue biospecimen ordinal  195 CMDC sample ID  196 BPC submitter ID (if available)  197 OTHER tissue sample CTryopreserved  198 Cryopreserved  199 CTHER tissue sample CTRYOTE SAME A CTRYOTE SAME AND CARREST CONTRACTOR TO SAME		sample?				
OTHER tissue biospecimen ordinal  Description of the sequence			⊔ NO			
194 OTHER tissue biospecimen ordinal    195						
biospecimen ordinal    biospecimen ordinal	194	OTHER tissue			6584267	-
sequence. Note: The first biospecimen sh be number "1," the second should be num "2," etc.  195	1 234				0304207	
be number "1," the second should be num "2," etc.  195		S.OSPECIFICIT OF UITIGI				sequence. Note: The first biospecimen should
### 195 CMDC sample ID  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)  197 OTHER tissue sample Cryopreserved  198 CMDC sample ID  6584015 Please provide the BPC.  6584919 Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted the BPC.  197 OTHER tissue sample Cryopreserved  5432521 Provide the method used to preserved						be number "1," the second should be number
for this specimen as it will appear on tubes and the Sample Submission Format transmitted to the BPC.  196 BPC submitter ID (if available)  BPC submitter ID (if available)  Cryopreserved  for this specimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.  5432521 Provide the method used to preserved						
tubes and the Sample Submission Form transmitted to the BPC.  196 BPC submitter ID (if available)  BPC submitter ID (if available)  Cryopreserved  197 OTHER tissue sample  Lubes and the Sample Submission Form transmitted to the BPC.  198 tubes and the Sample Submission Form transmitted to the BPC.  199 The sample Submission Form transmitted to the BPC.  190 The sample Submission Form transmitted to the BPC.  190 The sample Submission Form transmitted to the BPC.	195	CMDC sample ID			6586035	
transmitted to the BPC.  196 BPC submitter ID (if available)  BPC submitter ID (if available)  Cryopreserved  transmitted to the BPC.  6584919 Please provide the BPC-generated ID for this sample as it will appear on the Sample Submission Form transmitted the BPC.  197 OTHER tissue sample						
196 BPC submitter ID (if available)  BPC submitter ID (if this sample as it will appear on the Sample Submission Form transmitted the BPC.  197 OTHER tissue sample  Cryopreserved  5432521 Provide the method used to preserve						· ·
available)  this sample as it will appear on the Sample Submission Form transmitted the BPC.  197 OTHER tissue sample □ Cryopreserved 5432521 Provide the method used to preserve						
Sample Submission Form transmitted the BPC.  197 OTHER tissue sample	196	•			6584919	
the BPC.  197 OTHER tissue sample		available)				
197 OTHER tissue sample						1
	40-	OTHER #:	П 6		E 422521	
OTHER C.	197				5432521	
preservation method		preservation method				•
☐ Frozen molecular characterization.						molecular characterization.
☐ Snap frozen			☐ Snap frozen			

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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	☐ Needle biopsy		6587398	Provide the procedure performed to
	sample procurement	☐ Lumpectomy			obtain the OTHER tissue. Note: If the
		☐ Simple mastector	ny		method of procurement is not listed, proceed
		☐ Modified radical n	nastectomy		to Question 198a, otherwise, skip to Question
		☐ Other (specify)			199.
198a	Specify method of OTHER			6587399	Specify the procedure performed to
	tissue sample				obtain the OTHER tissue.
	procurement	-			
199	Number of days from			3288495	Provide the number of days from the
	index date to date of				index date to the date of the procedure
	OTHER sample				that produced the OTHER tissue
	procurement				submitted for HCMI.
200	Tissue type			64784	Indicate the OTHER tissue type.
		☐ Non-malignant			Note: If the OTHER tissue type is not listed,
		☐ Other (specify)			proceed to Question 200a, otherwise, skip to
200-	Consider tingers to use			64785	Question 201.
200a	Specify tissue type			64785	Specify the OTHER tissue type
					if not in the provided list.
201	Anatomic site of OTHER	☐ Left breast		6696813	Select the site from which the OTHER
201	tissue	☐ Right breast	☐ Lung	0030813	tissue used to develop the model was
	tissue	☐ Right breast ☐ Bone	☐ Lymph node		derived.
		☐ Brain	☐ Skin		Note: If the OTHER tissue site is not listed,
		Liver	☐ Other (specify)		proceed to Question 201a, otherwise, skip to
		Livei	— other (speeny)		Question 202.
201a	Specify anatomic site of			6584916	Specify the site of OTHER tissue, if not in
	OTHER tissue				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 Tissu	ue Model Information				
204	OTHER tissue model			6594590	Please provide a number to identify
	biospecimen ordinal				which biospecimen this is in the
					sequence. Note: The first biospecimen should
					be number "1," the second should be number
205	CMDC a dal ID			CE0C02C	"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	PDC submitter ID /if			6584919	
206	BPC submitter ID (if available)			0384919	Please provide the BPC-generated ID for this sample as it will appear on the
	avallable)				Sample Submission Form transmitted
					to the BPC.
207	Model's OTHER tissue			6586035	Enter the CMDC Sample ID of the OTHER
207	CMDC sample ID			0300033	tissue from which this model is derived.
	CiviDC sample ID				ussue from which this model is derived.
208	Model's OTHER tissue			6584267	Enter the biospecimen ordinal of the
200	biospecimen ordinal			0304207	OTHER tissue from which this model is
	Sidapecinien ordinar				derived.
Additional	Other Tissue Model Informa	ition (if annlicable)		L	derived.
209	OTHER tissue model	and it applicable)		6594590	Please provide a number to identify which
203	biospecimen ordinal			0004000	biospecimen this is in the sequence.
	Sisspecimen ordinar				Note: The first biospecimen should be number
		i		1	"1," the second should be number "2," etc.

	Enrollment: Breast	Political Control	20	
Tissue Source Site (TSS) Name:	HCMI Identifier (ID3):	To See	43	-
Completed By:	Completion Date (MM/DD/YYYY):	a b	3	

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