/1.0		
71.0	Enrollment: Head and Neck	
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
				treatment). Date of initial pathologic
		☐ Initial pathologic diagnosis		diagnosis is the HCMI standard and
		☐ Sample procurement		should be used unless it is
		☐ First patient visit		unavailable. If an alternative index
				date is used, indicate it here and use
				it for all interval calculations.
Patient Inf	formation		<u>'</u>	
4	Gender		2200604	Provide the patient's gender using
				the defined categories.
		☐ Male		Identification of gender is based
		Female		upon self-report and may come
		☐ Unspecified		from a form, questionnaire,
				interview, etc.
5	Height		649	Provide the patient's height, in
	Ŭ			centimeters.
6	Weight		651	Provide the patient's weight, in
				kilograms.
7	Body mass index (BMI)		2006410	If the patient's height and weight
	,			are not collected, provide the
				patient's body mass index (BMI).
8	Race		2192199	Provide the patient's race using the
_	1.000			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
		☐ Black or African American		in the Indian subcontinent including, for
		☐ Native Hawaiian or other Pacific Islander		example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine
		☐ White		Islands, Thailand, and Vietnam.
		☐ Unknown		Black or African American: A person having
		☐ Not reported		origins in any of the black racial groups of
				Africa.
				Native Hawaiian or other Pacific Islander:
				A person having origins on any of the original peoples of Hawaii, Guam, Samoa,
				or other Pacific Island.
				White: A person having origins in any of the
				original peoples of Europe, the Middle East,
	Falls of all to		2402247	or North Africa.
9	Ethnicity		2192217	Provide the patient's ethnicity using
		□ Hispania on Latina		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		Not Hispanic or Latino: A person not
				meeting the definition of Hispanic or Latino.

	Enrollment: Head and Neck	
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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. Note: If the patient has a smoking history, proceed to Question 15, otherwise, skip to Question 17.
15	Number pack years smoked		2955385	Indicate the number of pack years smoked. (Numeric computed value to represent lifetime tobacco exposure defined as number of cigarettes smoked per day x number of years smoked divided by 20.)
16	Tobacco smoking quit year		2228610	Indicate the year in which the participant quit smoking.
17	Alcohol exposure intensity	<ul> <li>□ Not evaluated</li> <li>□ Lifetime non-drinker</li> <li>□ Non-drinker</li> <li>□ Daily drinker</li> <li>□ Weekly drinker</li> </ul>	3457767	Select the patient's current level of alcohol use as self-reported by the patient. Note: If the patient drinks alcohol, proceed to Question 18, otherwise, skip to Question 21.
18	Alcohol type	☐ Beer ☐ Liquor ☐ Wine ☐ Other (specify)	2201970	Select all types of alcohol consumed as self-reported by the patient.
18a	Specify other alcohol type		6788013	If not included in the previous list, provide all types of alcohol consumed as self-reported by the patient.
19	Amount of alcohol consumption per day	drinks per day	3124961	Provide the average number of alcoholic beverages that the patient reports consuming per day.
20	Amount of alcohol consumption per week	drinks per week	3114013	Provide the average number of days each week that the patient consumes an alcoholic beverage.
21	Did the patient ever use smokeless tobacco (including chewing tobacco and snuff) regularly for a period of six weeks or more?	☐ Yes ☐ No ☐ Unknown	3624720	Indicate whether or not the patient used smokeless tobacco regularly for a period of six weeks or more.  Note: If the patient used smokeless tobacco, proceed to Question 22, otherwise, skip to Question 25.

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Tissue Source Site (TSS) Name:	HCMI Identifier (ID3):
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smokeless tobacco (including chewing tobacco and snuff) regularly for at least six weeks, on average how many times per day did they use?  23 If the patient used smokeless tobacco (including chewing tobacco and snuff) regularly for at least six weeks, how old were they when they started using?  24 If the patient used smokeless tobacco (including chewing tobacco and snuff) regularly for at least six weeks, how old were they when they started using?  25 Is the patient currently using marijuana?  26 Marijuana usage per week  27 Did the patient ever use e-cigarettes regularly for a period of six weeks or more?  28 Number of days e- cigarettes were used in the last 30 days.  29 Asbestos exposure?    Yes	Question	Question Text	Data Entry Options	CDE ID	Instruction Text
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they when they quit using?  25  Is the patient currently using marijuana?					
Using?   Section   Secti					
25					
No	25			6788017	Indicate whether the patient is
Unknown   Question 26, otherwise, skip to Que 27.		using marijuana?			currently using marijuana. Note: If
27.  26 Marijuana usage per week  27 Did the patient ever use e-cigarettes regularly for a period of six weeks or more?  28 Number of days e-cigarettes were used in the last 30 days  29 Asbestos exposure?  30 Is the patient HIV-positive?  27 Did the patient ever use e-cigarettes regularly for a period of six week or more. Note: If the patient has been diagnosed with Human Immunodeficiency Virus (HIV). A If the patient is HIV-positive, proceed.					
26   Marijuana usage per			Unknown		
Week.   Week.   Week.     Week.       Week.	26	Marijuana usage per		6788018	Indicate the total number of times
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a period of six weeks or more?  No Unknown  Rote: If the patient used ecigarettes, proceed to Question 28, otherwise, skip to Question 29.  Number of days ecigarettes were used in the last 30 days  Pes Rote: If the patient used ecigarettes, proceed to Question 29.  Indicate the number of days that patient used electronic cigarette within the last 30 days.  Pes Rote: If the patient used ecigarettes, proceed to Question 29.  Indicate the number of days that patient used electronic cigarette within the last 30 days.  Pes Rote: If the patient used ecigarettes within the last 30 days.  Specify if the patient has been exposed to asbestos.  Indicate whether the patient has been diagnosed with Human lmmunodeficiency Virus (HIV). No lf the patient is HIV-positive, proceed.	27	-		6788019	-
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Common   C			□ No		
Otherwise, skip to Question 29.		mores	☐ Unknown		
cigarettes were used in the last 30 days  29 Asbestos exposure?					
the last 30 days  29 Asbestos exposure?	28	Number of days e-		6788020	Indicate the number of days that the
29 Asbestos exposure?		S .			patient used electronic cigarettes
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positive?  Yes  No  Immunodeficiency Virus (HIV). No  If the patient is HIV-positive, process	30	Is the natient HIV-	Oliknown	3196353	Indicate whether the nationt has
□ No □ High pown	30	T	□ Vas	3130333	I
If the patient is HIV-positive, proceed		, positive.			Immunodeficiency Virus (HIV). <i>Note:</i>
Question 31, otherwise, skip to Que					If the patient is HIV-positive, proceed to
1 1 22			- Onknown		Question 31, otherwise, skip to Question
31 CD4 count 4182751 Indicate the result of the process	31	CD4 count		4182751	Indicate the result of the procedure
· · · · · · · · · · · · · · · · · · ·		CD T COUNT		7102/31	used to determine the number of
					CD4+ T-cells in the patient's sample.
32 Metastasis at diagnosis 3438571 Indicate whether there was	32	Metastasis at diagnosis		3438571	
		assessment status	D Martinetti		evidence of metastasis at the time
					of diagnosis of the primary tumor.
□ Non-metastatic (confirmed) □ Non-metastatic (unconfirmed)					Note: If metastatic at diagnosis, proceed to Question 33, otherwise, skip
to Question 34.			— 1301 metastatic (ancommea)		

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diagnosis	ate the site(s) of metastasis at me of diagnosis of the primary r. Note: If the anatomic site of a tissue is not listed, proceed to ion 33a, otherwise, skip to ion 34.  Site of metastasis is not ded on the provided list, specify the of metastasis.  The select all the tissue sample submitted for HCMI with this are provided the number of all tissue specimens obtained CMI for this case. Note: This per is expected to be 1.  The provide the number of ary tumor specimens obtained CMI for this case. Note: A single
Liver   Mediastinum   Lumon	r. Note: If the anatomic site of tissue is not listed, proceed to ion 33a, otherwise, skip to ion 34.  site of metastasis is not ded on the provided list, specify te of metastasis.  e select all the tissue sample submitted for HCMI with this  e provide the number of all tissue specimens obtained CMI for this case. Note: This er is expected to be 1.  e provide the number of ary tumor specimens obtained CMI for this case. Note: A single
Mediastinum	rtissue is not listed, proceed to ion 33a, otherwise, skip to ion 34.  site of metastasis is not ded on the provided list, specify te of metastasis.  e select all the tissue sample submitted for HCMI with this  e provide the number of all tissue specimens obtained CMI for this case. Note: This er is expected to be 1.  e provide the number of ary tumor specimens obtained CMI for this case. Note: A single
Bone marrow   Lymph node(s): non-regional   Lymph node(s): regional   Lymph node(s): regional   Other (specify)   Specify metastatic site(s)   Sp	site of metastasis is not ded on the provided list, specify te of metastasis.  e select all the tissue sample submitted for HCMI with this e provide the number of all tissue specimens obtained CMI for this case. Note: This er is expected to be 1.  e provide the number of ary tumor specimens obtained CMI for this case. Note: A single
Lymph node(s): non-regional   Lymph node(s): regional   Lymph node(s): regional   Other (specify)   3128033   If the including the size   Si	site of metastasis is not ded on the provided list, specify te of metastasis.  e select all the tissue sample submitted for HCMI with this e provide the number of all tissue specimens obtained CMI for this case. Note: This er is expected to be 1.  e provide the number of ary tumor specimens obtained CMI for this case. Note: A single
Lymph node(s): regional   Other (specify)	ded on the provided list, specify te of metastasis.  e select all the tissue sample submitted for HCMI with this e provide the number of al tissue specimens obtained CMI for this case. Note: This er is expected to be 1.  e provide the number of ary tumor specimens obtained CMI for this case. Note: A single
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Biospecimen Information  34 Tissue sample type(s)	ded on the provided list, specify te of metastasis.  e select all the tissue sample submitted for HCMI with this e provide the number of al tissue specimens obtained CMI for this case. Note: This er is expected to be 1.  e provide the number of ary tumor specimens obtained CMI for this case. Note: A single
Biospecimen Information  34 Tissue sample type(s)	te of metastasis.  e select all the tissue sample submitted for HCMI with this e provide the number of al tissue specimens obtained CMI for this case. Note: This er is expected to be 1.  e provide the number of ary tumor specimens obtained CMI for this case. Note: A single
Biospecimen Information  34 Tissue sample type(s)	e select all the tissue sample submitted for HCMI with this e provide the number of al tissue specimens obtained CMI for this case. Note: This er is expected to be 1. e provide the number of ary tumor specimens obtained CMI for this case. Note: A single
34 Tissue sample type(s) □ Normal tissue □ Recurrent □ Other tissue □ Stypes case.  35 Number of NORMAL tissues biospecimens collected for HCMI for this case □ Metastatic □ Other tissue □ Stypes case.  36 Number of PRIMARY cancer tissue □ Recurrent □ Other tissue □ Recurrent □ Other tissue	e provide the number of al tissue specimens obtained CMI for this case. Note: This er is expected to be 1.  e provide the number of ary tumor specimens obtained CMI for this case. Note: A single
collected for HCMI for this case   Primary tumor Other tissue   Case.    35  Number of NORMAL tissues biospecimens collected for HCMI for this case   Mumber of PRIMARY cancer tissue	e provide the number of al tissue specimens obtained CMI for this case. Note: This er is expected to be 1.  e provide the number of ary tumor specimens obtained CMI for this case. Note: A single
this case	e provide the number of al tissue specimens obtained CMI for this case. Note: This er is expected to be 1.  e provide the number of ary tumor specimens obtained CMI for this case. Note: A single
tissues biospecimens collected for HCMI for this case  Number of PRIMARY cancer tissue  norm for H number 6584257 Pleas prima	al tissue specimens obtained CMI for this case. Note: This er is expected to be 1. e provide the number of ary tumor specimens obtained CMI for this case. Note: A single
collected for HCMI for this case for HCMI for number of PRIMARY cancer tissue for HCMI for hounds for H number of PRIMARY for this case for HCMI for hounds for HCMI for H number of PRIMARY for HCMI for	CMI for this case. Note: This er is expected to be 1. e provide the number of ary tumor specimens obtained CMI for this case. Note: A single
this case number of PRIMARY cancer tissue 6584257 Pleas prima	er is expected to be 1.  e provide the number of eary tumor specimens obtained CMI for this case. Note: A single
36 Number of PRIMARY 6584257 Pleas prima	e provide the number of ary tumor specimens obtained CMI for this case. <i>Note: A single</i>
cancer tissue prima	ary tumor specimens obtained CMI for this case. <i>Note: A single</i>
	CMI for this case. Note: A single
blospecimens confected	_
	y tumor biospecimen obtained that is
development for this portion	ned for both sequencing and model
genero	tion counts as 1 single primary tumor en. This number is expected to be 1.
	e provide the number of
RECURRENT cancer meta	static and/or recurrent cancer
	ecimens collected for HCMI for
	ase. Note: A biospecimen obtained
progre	single site at a single timepoint in ssion that is portioned for both
	cing and model generation counts as 1
	tumor specimen. A biospecimen ed from another site or at a later
timepo	int in progression that is portioned for
	equencing and model generation as a second single tumor specimen.
	e provide the number of pre-
	nant, non-malignant, or
for HCMI model dyspl	astic tissue biospecimens
	cted for HCMI for this case.
	A biospecimen obtained from a site at a single timepoint in
	ession that is portioned for both
	ncing and model generation counts
	ngle tumor specimen. A biospecimen ed from another site or at a later
	oint in progression that is portioned
	th sequencing and model generation
	e provide the total number of
	e biospecimens collected for
	for this case. Note: This number
	be the sum of the normal, primary
	metastatic/ recurrent tumor, and piospecimen counts above.
Normal Control Information	•
	e provide a number to identify
	n biospecimen this is in the
	ence. Note: The first biospecimen be number "1," the second should be
	er "2," etc.

# **Enrollment: Head and Neck**

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
41	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.
42	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.
43	Type of normal control	<ul> <li>□ Whole blood</li> <li>□ Buccal cells</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>□ Adjacent normal tissue (specify)</li> <li>□ Contralateral normal tissue (specify)</li> <li>□ FFPE non-neoplastic tissue (specify)</li> <li>□ Non-neoplastic tissue (specify)</li> </ul>	3081936	Indicate the type of normal control submitted for this case.
44	Anatomic site of normal tissue	□ Lip       □ Subglottis         □ Oral tongue, anterior       □ Nasal cavity Paranasal sinus(es)         □ Skin       □ Parotid gland         □ Oropharynx       □ Submandibular gland         □ Nasopharynx       □ Sublingual gland         □ Supraglottis       □ Other (specify)         □ Glottis       □ 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 44a, otherwise, skip to Question 45.
44a	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.
45	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'.
Primary T	Normal tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the normal tissue sample collected for molecular characterization.
47	Imor Biospecimen Information  Head and neck cancer	on  Lip and Oral cavity	2179718	Select the anatomic site of origin for
4/	region	<ul><li>□ Pharynx</li><li>□ Larynx</li><li>□ Paranasal sinuses and nasal cavity</li><li>□ Salivary glands</li></ul>		the head and neck cancer in the patient.
48	ICD-10 code for primary tumor	□ C00.0       □ C03.9       □ C08.9       □ C13.2         □ C00.1       □ C04.0       □ C09.0       □ C13.8         □ C00.2       □ C04.1       □ C09.1       □ C13.9         □ C00.3       □ C04.8       □ C09.8       □ C14.0         □ C00.4       □ C04.9       □ C09.9       □ C30.0         □ C00.5       □ C05.0       □ C10.1       □ C31.0         □ C00.6       □ C05.1       □ C10.2       □ C31.1         □ C00.8       □ C05.2       □ C10.3       □ C31.2	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 48a, otherwise, skip to Question 49.  Page 5 of 35

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	ce Site (TSS) Name: By:		
		□ C00.9       □ C05.8       □ C10.8       □ C31.3         □ C01       □ C05.9       □ C10.9       □ C31.8         □ C02.0       □ C06.0       □ C11.0       □ C31.9         □ C02.1       □ C06.1       □ C11.1       □ C32.0         □ C02.2       □ C06.2       □ C11.2       □ C32.1         □ C02.3       □ C06.8       □ C11.3       □ C32.2         □ C02.4       □ C06.9       □ C11.8       □ C32.3         □ C02.8       □ C07       □ C11.9       □ C32.8         □ C02.9       □ C08.0       □ C12       □ C32.9         □ C03.0       □ C08.1       □ C13.0       □ Other         □ C03.1       □ C08.8       □ C13.1       (specify)	
48a	Other ICD-10 code for primary tumor		226287 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.
49	Tumor morphology	□       8070/3       □       8083/3       □       8525/3       32         □       8041/3       □       8147/3       □       8550/3       □         □       8051/3       □       8200/3       □       8560/3       □         □       8052/3       □       8310/3       □       8562/3       □         □       8073/3       □       8340/4       □       8720/3       □         □       8074/3       □       8430/3       □       8982/3       □       Other         □       8082/3       □       8523/3       (specify)       □	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 49a, otherwise, skip to Question 50.
49a	Specify other morphology		226275 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.
50	Tissue or organ of origin	☐ Lip ☐ Paranasal sinuses ☐ Oral cavity ☐ Nasal cavity ☐ Pharynx ☐ Salivary gland ☐ Larynx ☐ Other (specify)	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 50a, otherwise skip to Question 51.
50a	Other tissue or organ of origin		If the primary site of the disease is not included on the previous list, provide the primary site of the disease.
51	Histological type	☐ Head and neck cancer ☐ Other (specify)	O81932 Select the surgical pathology text description of the histological tumor type. Note: If the histological tumor type is not listed, proceed to Question 51a, otherwise, skip to Question 52.
51a	Other histological type		294805 If the traditional surgical pathology text description of the histological tumor type is not included on the previous list, specify the histological type.
52	Histological subtype	<ul> <li>□ Acantholytic squamous cell carcinoma</li> <li>□ Acinic cell carcinoma</li> <li>□ Adenocarcinoma, non-salivary gland type</li> <li>□ Adenocarcinoma, NOS (specify low, intermediate, or high grade)</li> <li>□ Adenoid cystic carcinoma (specify tubular, cribriform, or solid pattern)</li> <li>□ Adenosquamous carcinoma</li> <li>□ Basal cell adenocarcinoma</li> <li>□ Basaloid squamous cell carcinoma</li> <li>□ Biphenotypic sinonasal sarcoma</li> </ul>	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 52a, otherwise, skip to Question 53.

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	Enrollment: Head and Neck	
Tissue Source Site (TSS) Name:		
Completed By:	Completion Date (MM/DD/YYYY):	
	☐ Carcinoma cuniculatum	
	☐ Carcinosarcoma	
	☐ Clear cell carcinoma	
	☐ Epithelial-myoepithelial carcinoma	
	☐ HPV-mediated squamous cell carcinoma	
	☐ HPV-unrelated squamous cell carcinoma	
	☐ Hypopharyngeal squamous cell carcinoma	
	☐ Intestinal adenocarcinoma, colonic pattern	
	☐ Intestinal adenocarcinoma, mixed pattern	
	☐ Intestinal adenocarcinoma, mucinous pattern	
	☐ Intestinal adenocarcinoma, papillary pattern	
	☐ Intestinal adenocarcinoma, solid pattern	
	☐ Intraductal carcinoma, (specify low,	
	intermediate, or high grade)	
	☐ Large cell neuroendocrine carcinoma, HPV -	
	☐ Large cell neuroendocrine carcinoma, HPV +	
	Lymphoepithelial carcinoma	
	☐ Moderately differentiated neuroendocrine	
	carcinoma	
	☐ Mucoepidermoid carcinoma (specify low,	
	intermediate, or high grade)	
	☐ Mucosal melanoma	
	☐ Myoepithelial carcinoma	
	□ Nasopharyngeal papillary adenocarcinoma	
	□ Non-intestinal adenocarcinoma, (specify low,	
	intermediate, or high grade)	
	□ NUT carcinoma	
	☐ Oncocytic carcinoma ☐ Oropharyngeal squamous cell carcinoma, HPV	
	status unknown	
	☐ Papillary squamous cell carcinoma	
	☐ Polymorphous adenocarcinoma, classic	
	(specify low, intermediate, or high grade)	
	☐ Polymorphous adenocarcinoma, classic,	
	(specify low, intermediate, or high grade)	
	☐ Polymorphous adenocarcinoma, cribriform	
	(specify low, intermediate, or high grade)	
	☐ Poorly differentiated carcinoma, large cell	
	neuroendocrine	
	☐ Poorly differentiated carcinoma, small cell	
	neuroendocrine	
	☐ Poorly differentiated carcinoma,	
	undifferentiated	
	☐ Poorly differentiated neuroendocrine	
	carcinoma, large cell	
	☐ Poorly differentiated neuroendocrine	
	carcinoma, small cell	
	☐ Salivary duct carcinoma	
	☐ Sebaceous adenocarcinoma	
	☐ Secretory carcinoma	
	☐ Sinonasal undifferentiated carcinoma	
	☐ Small cell neuroendocrine carcinoma, HPV -	
	☐ Small cell neuroendocrine carcinoma, HPV +	
	☐ Spindle cell squamous cell carcinoma	
	☐ Squamous cell carcinoma, keratinizing	
	☐ Squamous cell carcinoma, nonkeratinizing	
	☐ Squamous cell carcinoma, primary	
	☐ Verrucous squamous cell carcinoma ☐ Well differentiated neuroendocrine carcinoma	
	☐ Well differentiated neuroendocrine carcinoma	

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



		☐ Other (spec	cify)			
52a	Other histological subtype				3124492	If the histological subtype for the primary tumor is not included in the provided list, specify the histological subtype.
53	For mucoepidermoid carcinoma, indicate the grade	☐ Low ☐ Intermedia ☐ High ☐ Unknown	te		6788058	Indicate the histologic grade of the Mucoepidermoid carcinoma.
54	For adenoid cystic carcinoma, indicate the pattern type	☐ Tubular☐ Cribriform☐ Solid			6788063	Indicate the morphological pattern of tumor growth for Adenoid cystic carcinoma.
55	For polymorphous adenocarcinoma, indicate the grade	☐ Low☐ Intermedia☐ High☐ Unknown	te		6788059	Indicate the histologic grade of the polymorphous adenocarcinoma.
56	For adenocarcinoma, NOS, indicate the grade	☐ Low ☐ Intermedia ☐ High ☐ Unknown	te		6788060	Indicate the histologic grade of the adenocarcinoma, NOS.
57	For intraductal carcinoma, indicate the grade	□ Low □ Intermedia □ High □ Unknown	te		6788061	Indicate the histologic grade of the intraductal carcinoma.
58	For non-intestinal adenocarcinoma, indicate the grade	☐ Low☐ Intermedia☐ High☐ Unknown	te		6788062	Indicate the histologic grade of the non-intestinal adenocarcinoma.
59	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.
60	Prior malignancy (other cancer type)	☐ Yes☐ No☐ Unknown			5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.
61	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.
62	Clinical stage group	☐ Stage 0 ☐ Stage I ☐ Stage II ☐ Stage III		Stage IVA Stage IVB Stage IVC	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).
63	AJCC pathologic spread: Primary tumor (pT)	☐ Tx ☐ Tis ☐ T0	□ T1 □ T2 □ T3	□ T4 □ T4a □ T4b	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).
64	AJCC pathologic spread: Lymph nodes (pN)	□ NX □ N0 □ N1 □ N2	□ N2a □ N2b □ N2c	□ N3 □ N3a □ N3b	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).

# **Enrollment: Head and Neck**

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
65	AJCC pathologic spread:	, ,	3045439	Using the patient's
	Distant metastases (pM)	Пмо		pathology/laboratory report, select
		□ M0		the code for the pathologic M
				(metastasis) as defined by the
		L IVIX		American Joint Committee on
				Cancer (AJCC).
66	Tumor stage		3065862	Using the patient's
	(pathological)	☐ Stage 0 ☐ Stage IVA		pathology/laboratory report, in
		☐ Stage I		conjunction with the patient's
		☐ Stage II		medical record, select the stage as
		☐ Stage III		defined by the American Joint
			2=2=22	Committee on Cancer (AJCC).
67	For squamous cell		2785839	Using the patient's
	carcinomas, tumor grade	□ G2 □ GX		pathology/laboratory report, select
	Engally and alleged band		2705020	the grade of the primary tumor.
68	For salivary gland head	☐ Low grade	2785839	Using the patient's
	and neck cancers, select the grade	☐ Intermediate grade		pathology/laboratory report, select the grade of the primary tumor.
	the grade	☐ High grade		the grade of the primary tumor.
Prognostic	 :/Predictive/Lifestvle Feature	। es for Primary Tumor Prognosis or Responsiveness t	o Treatment	
69	Tumor laterality		827	For a tumor in a paired organ,
	,	☐ Right ☐ Midline		designate the side of the body on
		☐ Left ☐ Not specified		which the tumor or cancer
		☐ Bilateral ☐ Not a paired site		developed.
70	Tumor focality	☐ Unifocal	3174022	Indicate whether the tumor or
		☐ Multifocal		cancer first developed in a single or
		☐ Cannot be determined		multiple locations.
71	Tumor size (greatest		64215	Provide the length of the largest
	dimension, cm)			dimension/diameter of a tumor, in
		cm		cm, regardless of anatomical plane.
72	Tumor depth of invasion		2182144	Provide the measurement in mm of
	(mm)	mm		the depth of invasion of the tumor.
73	Lymphovascular invasion	☐ Yes	64727	Indicate whether large vessel
	present?	□ No		(vascular) invasion or small, thin-
		☐ Indeterminate		walled (lymphatic) invasion was
7.4	Paris a constitue at a c	Unknown	64404	detected in the primary tumor.
74	Perineural invasion	☐ Yes ☐ No	64181	Indicate whether perineural invasion or infiltration of tumor or
	present?	☐ Unknown		I .
75	Number of positive	Olikilowii	89	cancer is present.  Provide the number of lymph nodes
/3	lymph nodes		83	with disease involvement.
76	Number of lymph nodes		3	Provide the total number of lymph
, ,	tested		3	nodes tested for the presence of
				cancer cells.
77	Extranodal extension	□ Present	65043	Indicate whether extranodal
		☐ Absent		extension of the cancer is present.
		☐ Unknown		<u> </u>
78	Residual tumor/margins	☐ RX (Presence of residual tumor cannot be	2608702	Indicate the status of the tissue
		addressed)		margin following surgical resection.
		☐ R0 (No residual tumor)		
		☐ R1 (Microscopic residual tumor)		
		☐ R2 (Macroscopic residual tumor)		
79	Margin distance (mm)		3915853	Provide the distance between the
				malignant neoplasm and the
		mm	670000	surgical margin in mm.
80	High-grade dysplasia in	☐ Present	6788003	Indicate whether high-grade
	mucosal resection	☐ Absent		dysplasia was detected within the
	margins	☐ Unknown		mucosal resection margins.

Tissue Source Site (TSS) Name:	HCMI Identifier (ID3):
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
81	Growth pattern of	□ Cohesive	6788004	Indicate the type of growth pattern
82	primary tumor	☐ Non-adhesive ☐ Yes	3626299	exhibited by the primary tumor.
82	Epstein-Barr virus infection	□ No	3626299	Indicate whether or not an Epstein- Barr virus infection occurred in the
	Intection	☐ Unknown		patient.
83	Was Epstein-Barr Virus	☐ Yes	6788005	Indicate whether Epstein-Barr Virus
	(EBV) early mRNA ISH	□ No		early mRNA status was assessed
	performed?	☐ Unknown		using an in situ hybridization (ISH)
84	Epstein-Barr Virus (EBV)	☐ Positive	6788006	assay. Indicate the Epstein-Barr Virus early
04	early mRNA status by ISH	☐ Negative	0788000	mRNA status detected by an in situ
		☐ Indeterminate		hybridization staining method.
85	Was p16 IHC performed?		6690713	Indicate whether or not
		☐ Yes		immunohistochemical analysis for a
		□ No		p16/CDKN2A mutation was
		☐ Unknown		performed. Note: If p16 IHC was performed, proceed to Question 86,
				otherwise, skip to Question 87.
86	p16 expression by IHC	☐ Positive	6690724	Indicate the status of the
		□ Negative		p16/CDKN2A protein expression
87	Was HPV-DNA ISH	☐ Equivocal	6788007	using immunohistochemistry. Indicate whether Human
87	performed?		6788007	Papillomavirus DNA status was
	performed:	□ Yes		assessed using an in situ
		□ No		hybridization (ISH) assay. Note: If
		☐ Unknown		HPV-DNA ISH was performed, proceed
				to Question 88, otherwise, skip to Question 89.
88	HPV-DNA status by ISH	☐ Positive	6788008	Indicate the Human Papillomavirus
	,	☐ Negative		DNA status as detected by an in situ
		☐ Indeterminate		hybridization staining method.
89	Was HPV-E6/E7 mRNA		6788009	Indicate whether Human
	ISH performed?	☐ Yes		Papillomavirus E6/E7 status was assessed using an in situ
		□ No		hybridization (ISH) assay. <i>Note: If</i>
		☐ Unknown		HPV-E6/E7 mRNA ISH was performed,
				proceed to Question 90, otherwise, skip to Question 91.
90	HPV-E6/E7 mRNA status		6788010	Indicate the Human Papillomavirus
30	by ISH	Positive	0,00010	E6/E7 mRNA status as detected by
		☐ Negative ☐ Indeterminate		an in situ hybridization staining
		Indeterminate		method.
91	Was HPV-DNA PCR		6788011	Indicate whether or not Human
	performed?	☐ Yes		Papillomavirus DNA status was assessed by polymerase chain
		□ No		reaction. <i>Note: If HPV-DNA PCR was</i>
		☐ Unknown		performed, proceed to Question 92,
	LIBY DATA A A DOD		6700015	otherwise, skip to Question 93.
92	HPV-DNA status by PCR	☐ Positive	6788015	Indicate the Human Papillomavirus DNA status detected by reverse
		☐ Negative		transcriptase-polymerase chain
		☐ Indeterminate		reaction method.
93	Was HPV-E6/E7 mRNA		6788012	Indicate whether Human
	RT-PCR performed?			Papillomavirus E6/E7 mRNA status
		☐ Yes		was assessed using a polymerase
		□ No		chain reaction assay. Note: If HPV- E6/E7 mRNA RT-PCR was performed,
		☐ Unknown		proceed to Question 94, otherwise, skip
				to Question 95.
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# **Enrollment: Head and Neck**

Tissue Source Site (TSS) Name: \_\_\_\_\_ HCMI Identifier (ID3): \_\_\_\_
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
94	HPV-E6/E7 mRNA status	☐ Positive	6788016	Indicate the Human Papillomavirus
	by RT-PCR	☐ Negative		E6/E7 mRNA status detected by
		☐ Indeterminate		reverse transcriptase-polymerase chain reaction method.
95	Additional pathologic	☐ Carcinoma in situ	6790126	Indicate all additional pathologic
	findings	☐ Colonization, bacterial ☐ Colonization, fungal		findings present in the patient. Note:  If the pathologic finding is not listed,
		Dysplasia, high grade		proceed to Question 95a, otherwise,
		Dysplasia, low grade		skip to Question 96.
		☐ Epithelial dysplasia		
		☐ Epithelial hyperplasia		
		☐ Hyperkeratosis		
		☐ Inflammation		
		☐ Keratinizing dysplasia, mild ☐ Keratinizing dysplasia, moderate		
		☐ Keratinizing dysplasia, moderate ☐ Keratinizing dysplasia, severe (carcinoma in		
		situ)		
		☐ None identified		
		☐ Nonkeratinizing dysplasia, mild		
		☐ Nonkeratinizing dysplasia, moderate		
		☐ Nonkeratinizing dysplasia, severe (carcinoma in situ)		
		☐ Sialadenitis		
		☐ Sinonasal papilloma		
		☐ Squamous metaplasia		
		☐ Squamous papilloma, solitary		
		☐ Squamous papillomatosis		
		☐ Tumor associated lymphoid proliferation☐ Other (specify)		
95a	Specify other additional	a other (specify)	6788022	If not included in the previous list,
	pathologic findings			specify any additional pathologic
				findings.
	ancer-specific Questions	D Nevertham was	2200000	In disable the subsection of the
96	If tumor is in the pharynx, in which	☐ Nasopharynx ☐ Hypopharynx	3380090	Indicate the subregion of the pharynx in which the patient's
	subregion?	Oropharynx		tumor is found.
	3401651011.	☐ Not applicable		tamor is round.
97	Occupational exposure	☐ Yes	4193912	Indicate whether the patient was
	to wood dust			exposed to wood dust in the
		☐ Unknown		workplace.
Larvny Car	 ncer-specific Questions			
98	Transglottic extension		6788023	Indicate whether a transglottic
		☐ Present		extension of the patient's laryngeal
		☐ Not identified		tumor was present.
Paranasal	Sinuses and Nasal Cavity Ca	 ncer-specific Questions	<u> </u>	
NUT Ca	rcinoma-specific Questions			
99	Was NUT IHC	☐ Yes	6788024	Indicate whether NUTM1 protein
	performed?	□ No		expression by
		☐ Unknown		immunohistochemistry (IHC) analysis was performed. <i>Note: If NUT</i>
				IHC was performed, proceed to
				Question 100, otherwise, skip to
				Question 101.
100	NUT expression by IHC	Positive	6788028	Indicate the status of the NUTM1
		☐ Negative ☐ Equivocal		protein expression using immunohistochemistry.
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
101	Was NUT translocation	☐ Yes	6788032	Indicate whether an analysis for
	analysis performed?	□ No		translocation in the NUTM1 gene
		☐ Unknown		was performed. Note: If NUT
				translocation analysis was performed,
				proceed to Question 102, otherwise,
102	NA/ NILITAGE AL	П V	6700000	skip to Question 104.
102	Was a NUT translocation identified?	☐ Yes ☐ No	6788038	Indicate whether a NUTM1
	identified?	□ NO		chromosomal translocation was
				identified. Note: If a NUT translocation was identified, proceed to Question 103,
				otherwise, skip to Question 104.
103	If translocation identified	□ NUT-BRD4	6788044	Select the translocation identified
103	with NUT, which one?	☐ Other translocation (specify)	0700044	with the NUTM1 gene. <b>Note: If the</b>
	with ito i, which one.	— Other transfocation (specify)		NUT translocation is not listed, proceed
				to Question 103a, otherwise, skip to
				Question 104.
103a	Specify other NUT		6788055	If not included in the previous list,
	translocation			provide the translocation identified
		<del></del>		with the NUTM1 gene.
Sinonas	al Undifferentiated Carcinor	na-specific Questions		
104	Was INI-1 IHC	☐ Yes	6788025	Indicate whether INI-1 (SMARCB1)
	performed?	□ No		protein expression by immunohisto-
		☐ Unknown		chemistry (IHC) analysis was
				performed. Note: If INI-1 IHC was
				performed, proceed to Question 105,
				otherwise, skip to Question 106.
105	INI-1 expression by IHC	☐ Positive	6788029	Indicate the status of the INI-1
		☐ Negative		(SMARCB1) protein expression using
		☐ Equivocal		immunohistochemistry.
-	typic Sinonasal Sarcoma-sp		_	
106	Was PAX3 translocation	☐ Yes	6788033	Indicate whether an analysis for
	analysis performed?	□ No		translocation in the PAX3 gene was
		☐ Unknown		performed. Note: If PAX3 translocation
				analysis was performed, proceed to
				Question 107, otherwise skip to
407	M DAV2	П у	6700000	question 109.
107	Was a PAX3	☐ Yes	6788039	Indicate whether a PAX3
	translocation identified?	□ No		chromosomal translocation was
				identified. Note: If a PAX3
				translocation was identified, proceed to Question 108, otherwise, skip to
				Question 109.
108	If translocation identified	□ PAX3-MAML3	6788045	Select the translocation identified
	with PAX3, which one?	☐ Other translocation (specify)		with the PAX3 gene. Note: If the PAX3
		= caner aramorodation (opcomy)		translocation is not listed, proceed to
				Question 108a, otherwise skip to
				Question 109.
108a	Specify other PAX3		6788050	If not included in the previous list,
	translocation			provide the translocation identified
		_ <del></del>		with the PAX3 gene.
	and Cancer-specific Question		T	
109	High grade	☐ Present	6788056	Indicate the high grade
	transformation	☐ Not identified		transformation status of the salivary
		□ Not applicable		gland tumor.
	ell Carcinoma-specific Questi		T	
110	Was EWSR1	Yes	6788034	Indicate whether an analysis for
	translocation analysis	□ No		translocation in the EWSR1 gene
	performed?	☐ Unknown		was performed. Note: If EWSR1
				translocation analysis was performed,
				proceed to Question 111, otherwise, skip to Question 113.
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	Enrollment: Head and Neck	A Policy Control	VV	190	
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
111	Was an EWSR1		6788040	Indicate whether an EWSR1
	translocation identified?			chromosomal translocation was
		☐ Yes		identified. Note: If an EWSR1
		□ No		translocation was identified, proceed to
				Question 112, otherwise, skip to Question 113.
112	If translocation identified		6788046	Select the translocation identified
112	with EWSR1, which one?	D EMCDA ATEA	0700040	with the EWSR1 gene. <i>Note: If the</i>
		☐ EWSR1-ATF1 ☐ Other translocation		EWSR1 translocation is not listed,
		Other translocation		proceed to Question 112a, otherwise
110	0 16 11 5111054		6700074	skip to Question 113.
112a	Specify other EWSR1		6788051	If not included in the previous list,
	translocation			provide the translocation identified with the EWSR1 gene.
				with the EWSKI gene.
Secretor	। ry Carcinoma-specific Questi	ions		
113	Was ETV6 translocation		6788035	Indicate whether an analysis for
	analysis performed?	☐ Yes		translocation in the ETV6 gene was
		□ No		performed. Note: If ETV6 translocation
		☐ Unknown		analysis was performed, proceed to
				Question 114, otherwise, skip to Question 116.
114	Was an ETV6		6788041	Indicate whether an ETV6
	translocation identified?			chromosomal translocation was
		☐ Yes		identified. Note: If an ETV6
		□ No		translocation was identified, proceed to
				Question 115, otherwise, skip to
115	If translocation identified		6788047	Question 116. Select the translocation identified
115	with ETV6, which one?	_	0/8804/	with the ETV6 gene. <i>Note: If the ETV6</i>
	with Livo, which one:	☐ ETV6-NTRK3		translocation is not listed, proceed to
		☐ Other translocation (specify)		Question 115a, otherwise skip to
				Question 116.
115a	Specify other ETV6		6788052	If not included in the previous list,
	translocation			provide the translocation identified
Mussam	idayyadid Cayainayya ayaaifi	- Overstions		with the ETV6 gene.
116	nidermoid Carcinoma-specific Was MAML2	t Questions	6788036	Indicate whether an analysis for
110	translocation analysis		0788030	translocation in the MAML2 gene
	performed?	□ Yes		was performed. Note: If MAML2
	F	□ No		translocation analysis was performed,
		☐ Unknown		proceed to Question 117, otherwise,
				skip to Question 119.
117	Was a MAML2		6788042	Indicate whether a MAML2
	translocation identified?		3.00012	chromosomal translocation was
		│		identified. Note: If a MAML2
		□ No		translocation was identified, proceed to
		- NO		Question 118, otherwise, skip to
				Question 119.
118	If translocation identified		6788048	Select the translocation identified
	with MAML2, which one?	□ MANAL2 CRTC1	0.00010	with the MAML2 gene. <b>Note: If the</b>
	,	☐ MAML2-CRTC1 ☐ MAML2-CRTC3		MAML2 translocation is not listed,
		☐ Other translocation (specify)		proceed to Question 118a, otherwise,
		Stile: dansionation (specify)		skip to Question 119.
118a	Specify other MAML2		6788053	If not included in the previous list,
1100	translocation		0,00033	provide the translocation identified
				with the MAML2 gene.
				-

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Adenoio	Cystic Carcinoma-specific C	uestions		
119	Was MYB IHC performed?	☐ Yes ☐ No	6788026	Indicate whether MYB protein expression by immunohisto-chemistry (IHC) analysis was performed. <i>Note: If MYB IHC was</i>
		Unknown		performed, proceed to Question 120, otherwise, skip to Question 121.
120	MYB expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6788030	Indicate the status of the MYB protein expression using immunohistochemistry.
121	Was MYB translocation analysis performed?	☐ Yes☐ No☐ Unknown	6788037	Indicate whether an analysis for translocation in the MYB gene was performed. Note: If MYB translocation analysis was performed, proceed to Question 122, otherwise, skip to Question 124.
122	Was a MYB translocation identified?	☐ Yes ☐ No	6788043	Indicate whether a MYB chromosomal translocation was identified. Note: If a MYB translocation was identified, proceed to Question 123, otherwise, skip to Question 124.
123	If translocation identified with MYB, which one?	<ul><li>☐ MYB-NFIB</li><li>☐ Other translocation (specify)</li></ul>	6788049	Select the translocation identified with the MYB gene. Note: If the MYB translocation is not listed, proceed to Question 123a, otherwise, skip to Question 124.
123a	Specify other MYB translocation		6788054	If not included in the previous list, provide the translocation identified with the MYB gene.
Salivary	Duct Carcinoma-specific Qu	estions		
124	Was HER2 IHC performed?	☐ Yes☐ No☐ Unknown	6063454	Indicate whether HER2 expression was assessed by immunohisto-chemistry (IHC). Note: If HER2 IHC was performed, proceed to Question 125, otherwise, skip to Question 126.
125	HER2 expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	2957563	Indicate the expression of HER2 as assessed by immunohistochemistry (IHC).
126	Was HER2 FISH/CISH performed?	☐ Yes☐ No☐ Unknown	6063447	Indicate whether HER2 was assessed by fluorescence in situ hybridization (FISH) or chromogenic in situ hybridization (CISH). Note: If HER2 FISH/CISH was performed, proceed to Question 127, otherwise, skip to Question 132.
127	HER2 status by FISH/CISH	☐ Amplified ☐ Equivocal ☐ Not amplified	2854089	Select the HER2 status as assessed by FISH/CISH. Note: If HER2 is amplified, proceed to Question 128, otherwise, skip to Question 132.
128	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.
129	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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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
130	Number of cells counted		3087902	Provide the total number of cells
	for HER2 and centromere			counted to assess HER2 and
	17 copy numbers			Centromere 17 copy numbers.
131	HER2/neu chromosome		2497552	If HER2 and Centromere 17 copy
	17 signal ratio			number analyses were performed
				by FISH, provide the ratio of the
				outcomes of these tests.
132	Was Androgen Receptor	☐ Yes	6788027	Indicate whether Androgen
	IHC performed?	□ No		Receptor expression was assessed
		☐ Unknown		by immunohistochemistry (IHC).
				Note: If androgen receptor IHC was
				performed, proceed to Question 133, otherwise, skip to Question 134.
133	Androgen Receptor	☐ Positive	6788031	Indicate the expression of Androgen
133	expression by IHC	□ Negative	0788031	Receptor as assessed by
	expression by inc	☐ Equivocal		immunohistochemistry (IHC).
Drimary Tı	ımor Sample Information	Lquivocai	<u> </u>	inimunonistochemistry (inc).
134	Are you submitting a			If yes, proceed to question 135.
134	primary tumor tissue	□ Yes		If submitting a metastatic/recurrent
	sample for this case?	□ No		tumor biospecimen, proceed to
	·			Question 167.
135	Primary tumor		6584265	Please provide a number to identify
	biospecimen ordinal			which biospecimen this is in the
				sequence. Note: This number should be
				<i>"1"</i> .
136	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
127	DDC as has it to a ID /if		CE04010	BPC.
137	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.
138	Sample represents		6584730	
130	Sample represents primary diagnosis?		0364730	Does this primary tumor specimen represent the PRIMARY DIAGNOSIS
	primary diagnosis:	Yes		for this Case ID3? <b>Note: If no, continue</b>
		□ No		to Question 139, otherwise, skip to
				Question 140.
139	Specify the ICD-10 code		3226287	Provide the ICD-10 code for the
				primary tumor used to generate the
				model submitted to HCMI.
140	Tumor tissue sample	☐ Cryopreserved	5432521	Provide the method used to
	preservation method	☐ FFPE		preserve the tumor tissue sample
		☐ Frozen		collected for molecular
		□ ост		characterization.
		☐ Snap frozen		
141	Anatomic site from	☐ External upper lip	4214629	Select the anatomic site of the
	which the tumor was	☐ External lower lip		tumor tissue sample used to
	obtained: Lip and oral	☐ Mucosa of upper lip		generate the model for HCMI. Note:
	cavity	☐ Mucosa of lower lip		If the tissue or organ not listed, proceed
		☐ Commissure of lip		to Question 141a. Otherwise, skip to Question 142.
		☐ Lateral border of tongue		Question 142.
		☐ Ventral surface of tongue		
		☐ Dorsal surface of tongue		
		☐ Anterior two-thirds of tongue		
		☐ Upper gingiva		
		☐ Lower gingiva		
	i	☐ Anterior floor of mouth	I	

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	☐ Floor of mouth	
	☐ Hard palate	
	☐ Buccal mucosa	
	☐ Vestibule of mouth, maxillary	
	☐ Vestibule of mouth, mandibular	
	Alveolar process maxillary	

		☐ Hoor of mouth ☐ Hard palate ☐ Buccal mucosa ☐ Vestibule of mouth, maxillary ☐ Vestibule of mouth, mandibular ☐ Alveolar process, maxillary ☐ Alveolar process, mandibular ☐ Retromolar area ☐ Mandible ☐ Maxilla ☐ Other (specify)		
141a	Other anatomic site from which the tumor was obtained: Lip and oral cavity		5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.
142	Anatomic site from which the tumor was obtained: Pharynx	<ul> <li>□ Palatine tonsil</li> <li>□ Base of tongue, including lingual tonsil</li> <li>□ Soft palate</li> <li>□ Uvula</li> <li>□ Pharyngeal wall (posterior)</li> <li>□ Nasopharyngeal tonsils (adenoids)</li> <li>□ Piriform sinus</li> <li>□ Postcricoid</li> <li>□ Pharyngeal wall (posterior and/or lateral)</li> <li>□ Other (specify)</li> </ul>	4214629	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI. Note: If the tissue or organ not listed, proceed to Question 142a. Otherwise, skip to Question 143.
142a	Other anatomic site from which the tumor was obtained: Pharynx		5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.
143	Anatomic site from which the tumor was obtained: Larynx	□ Epiglottis, lingual aspect □ Epiglottis, laryngeal aspect □ Aryepiglottic folds □ Arytenoid(s) □ False vocal cord □ Larynx ventricle □ True vocal cord □ Anterior commissure of glottis □ Posterior commissure of glottis □ Glottis, with subglottic extension □ Subglottis □ Other (specify)	4214629	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI. Note: If the tissue or organ not listed, proceed to Question 143a. Otherwise, skip to Question 144.
143a	Other anatomic site from which the tumor was obtained: Larynx		5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.
144	Anatomic site from which the tumor was obtained: Paranasal sinuses and nasal cavity	□ Nasal septum □ Nasal floor □ Nasal lateral wall □ Nasal vestibule □ Nasal cavity, NOS □ Paranasal sinus(es), maxillary □ Paranasal sinus(es), ethmoid □ Paranasal sinus(es), frontal □ Paranasal sinus(es), sphenoid □ Other (specify)	4214629	Select the anatomic site of the tumor tissue sample used to generate the model for HCMI. Note: If the tissue or organ not listed, proceed to Question 144a. Otherwise, skip to Question 145.
144a	Other anatomic site from which the tumor was obtained: Paranasal sinuses and nasal cavity		5946219	If not provided in the previous list, provide the anatomic site of the tumor tissue sample used to generate the model for HCMI.

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145	Anatomic site from	☐ Parotid gland, superficial lobe	4214629	Select the anatomic site of the
	which the tumor was	☐ Parotid gland, deep lobe		tumor tissue sample used to
	obtained: Salivary glands	☐ Parotid gland, total		generate the model for HCMI. Note:
		☐ Submandibular gland		If the tissue or organ not listed, proceed
		☐ Sublingual gland		to Question 145a. Otherwise, skip to
		☐ Minor gland(s)		Question 146.
		☐ Other (specify)		
145a	Other anatomic site from		5946219	If not provided in the previous list,
	which the tumor was			provide the anatomic site of the
	obtained: Salivary glands			tumor tissue sample used to
				generate the model for HCMI.
146	Method of cancer	☐ Buccal mucosal resection	3103514	Provide the procedure performed to
	sample procurement	☐ Core needle biopsy		obtain the primary tumor tissue.
		☐ Endolaryngeal excision		Note: If the method of procurement is
		☐ Excision		not listed, proceed to Question 146a,
		☐ Fine needle aspirate		otherwise, skip to Question 147.
		☐ Glossectomy		
		☐ Incisional biopsy		
		☐ Laryngopharyngectomy		
		☐ Mandibulectomy		
		☐ Maxillectomy		
		☐ Neck (lymph node) dissection		
		☐ Palatectomy		
		☐ Parotidectomy, deep		
		☐ Parotidectomy, not specified		
		☐ Parotidectomy, superficial		
		☐ Parotidectomy, total		
		☐ Partial laryngectomy		
		☐ Partial maxillectomy		
		☐ Radical maxillectomy		
		☐ Resection, sublingual gland		
		☐ Resection, submandibular gland		
		☐ Supracricoid laryngectomy		
		☐ Supraglottic laryngectomy		
		☐ Tonsillectomy		
		☐ Total laryngectomy		
		☐ Transoral laser excision (glottis)		
		☐ Vertical hemilaryngectomy		
		☐ Other (specify)		
146a	Specify the other method		2006730	Specify the procedure performed to
	of tumor sample			obtain the primary tumor tissue, if
	procurement			not included in the previous list.
147	Number of days from		3288495	Provide the number of days from
	index date to date of			the index date to the date of the
	tumor sample			procedure that produced the tumor
	procurement			tissue submitted for HCMI.
148	Tumor tissue type	П	3288124	Provide the primary tumor tissue
	7,7	Primary		type for this sample.
		☐ Additional Primary		, ·
		□ NOS		
Primary Tu	mor Model Information			
149	Primary model		6594596	Please provide a number to identify
	biospecimen ordinal			which biospecimen this is in the
	-p			sequence. <i>Note: This number is</i>
				expected to be "1".
150	CMDC model ID		6586036	Please provide the CMDC model ID
130	SIMDE MODELLE		030000	for this sample 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
151	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.
152	Model represents primary diagnosis?	☐ Yes ☐ No	6584730	Does this MODEL represent the PRIMARY DIAGNOSIS for this Case ID3?
153	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.
154	Model's primary tumor biospecimen ordinal		6584265	Enter the biospecimen ordinal of the PRIMARY TUMOR TISSUE from which this model is derived.
Treatment	Information			,
155	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 156-164. Radiation therapy is addressed in Questions 165-166.
156	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 157-158. Hormone therapy is addressed in Questions 159-160. Immunotherapy is addressed in Questions 161-162. Targeted therapy is addressed in Questions 163-164.
157	Neoadjuvant chemotherapeutic regimen	☐ Cisplatin ☐ Carboplatin and Paclitaxel ☐ Docetaxel, Carboplatin, and Fluorouracil ☐ Carboplatin, Paclitaxel, and Cetuximab ☐ Carboplatin (Cisplatin), Fluorouracil, and Pembrolizumab ☐ Other (specify)	2853313	Select all chemotherapeutics used for neoadjuvant therapy. Note: If neoadjuvant chemotherapy was not given, skip to Question 159. If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 157a, otherwise, skip to Question 158.
157a	Other neoadjuvant chemotherapeutic regimen		62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapies administered.
158	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.
159	Hormone therapy	☐ Herceptin ☐ Androgen deprivation (specify) ☐ Other (specify)	2582817	Select the hormone therapy administered to the patient. Note: If hormone therapy was not given, skip to Question 161. If the androgen deprivation was given, proceed to Question 159a. If the hormone therapy is not listed, proceed to Question 159b, otherwise, skip to Question 160.
159a	Specify the androgen deprivation therapy		6942918	Specify the androgen deprivation therapies administered.
159b	Other hormone therapy		2405358	If the hormone therapy is not included in the provided list, specify hormone therapy.

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160	Days to hormone		5102411	Provide the number of days from
	therapy treatment from			the index date to the date of
	index date			treatment with hormone therapy.
161	Immunotherapy	<ul> <li>□ Pembrolizumab</li> <li>□ Nivolumab</li> <li>□ Cemiplimab</li> <li>□ Durvalumab</li> <li>□ Ipilimumab</li> <li>□ Tremelimumab</li> </ul>	6788001	Select the immunotherapy administered to the patient. Note: If immunotherapy was not administered, skip to Question 163. If the immunotherapy is not listed, proceed to Question 161a, otherwise, skip to Question 162.
		<ul><li>☐ Pembrolizumab plus Ipilimumab</li><li>☐ Durvalumab plus Tremelimumab</li><li>☐ Other (specify)</li></ul>		Question 102.
161a	Specify other immunotherapy		2953828	Provide the name of the immunotherapy administered to the patient.
162	Days to immunotherapy treatment from index date		5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
163	Targeted Therapy	□ Cetuximab     □ Cetuximab, Carboplatin (Cisplatin),     Fluorouracil     □ Cetuximab, Carboplatin, and Paclitaxel     □ Bevacizumab     □ Panitumumab     □ Lenvatinib     □ Afatinib     □ Other (specify)	6788000	Select the targeted therapy administered to the patient. Note: If targeted therapy was not administered, skip to Question 165. If the targeted therapy regimen is not listed, proceed to Question 163a, otherwise, skip to Question 164.
163a	Specify targeted therapy		4308476	Provide the name of the targeted therapy administered to the patient.
164	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.
165	Radiation therapy administered type	□ Stereotactic Body □ 2D conventional RT □ 3D conformal □ Stereotactic □ Brachytherapy HDR Radiosurgery □ Brachytherapy LDR □ WBRT □ IMRT □ Other (specify) □ Proton Beam □ 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 167. If the radiation therapy is not listed, proceed to Question 165a, otherwise, skip to Question 166.
165a	Other radiation therapy		2195477	If the radiation therapy type is not included in the provided list, specify the type.
166	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.
Metastatio	c/Recurrent Tumor Biospecia	men Information	1	
167	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 168. If submitting an OTHER tissue sample, proceed to Question 256.
168	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.

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
169	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.
170	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.
171	Head and neck cancer region	☐ Lip and oral cavity ☐ Pharynx ☐ Larynx ☐ Paranasal sinuses and nasal cavity ☐ Salivary glands	2179718	Select the anatomic site of origin for the head and neck cancer in the patient.
172	Metastatic/recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
173	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.
174	Method of metastatic/ recurrent cancer sample procurement	□ Buccal mucosal resection □ Endolaryngeal excision □ Excision □ Glossectomy □ Incisional biopsy □ Laryngopharyngectomy □ Mandibulectomy □ Metastasectomy □ Metastasectomy □ Neck (lymph node) dissection □ Palatectomy □ Parotidectomy, deep □ Parotidectomy, not specified □ Parotidectomy, superficial □ Partial laryngectomy □ Partial maxillectomy □ Resection, sublingual gland □ Resection, submandibular gland □ Supracricoid laryngectomy □ Supraglottic laryngectomy □ Tonsillectomy □ Tonsillectomy □ Total laryngectomy □ Transoral laser excision (glottis) □ Vertical hemilaryngectomy □ Other Method (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. Note: If the method of procurement is not listed, proceed to Question 174a, otherwise, skip to Question 175.
174a	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.
175	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.

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Fissue Source Site (TSS) Name:	HCMI Identifier (ID3):	(XOY)	
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
176	Metastatic/recurrent site	☐ Alveolar process, mandibular	6587394	Select the site from which the
		☐ Alveolar process, maxillary		metastatic/recurrent tissue used to
		☐ Anterior commissure of glottis		develop the model was derived.
		☐ Anterior floor of mouth		Note: If the metastatic/recurrent site is
		☐ Anterior two-thirds of tongue		not listed, proceed to Question 176a, otherwise, skip to Question 177.
		☐ Aryepiglottic folds		otherwise, skip to Question 177.
		Arytenoid(s)		
		Base of tongue, including lingual tonsil		
		☐ Bone ☐ Bone marrow		
		☐ Bone marrow ☐ Buccal mucosa		
		☐ Commissure of lip		
		☐ Dorsal surface of tongue		
		☐ Epiglottis, laryngeal aspect		
		☐ Epiglottis, lingual aspect		
		☐ External lower lip		
		☐ External upper lip		
		☐ False vocal cord		
		☐ Floor of mouth		
		☐ Glottis, with subglottic extension		
		☐ Hard palate		
		☐ Larynx ventricle		
		☐ Lateral border of tongue		
		☐ Liver		
		☐ Lower gingiva		
		Lung		
		Lymph node(s), non-regional		
		Lymph node(s), regional		
		☐ Mandible		
		Maxilla		
		☐ Mediastinum		
		☐ Minor gland(s) ☐ Mucosa of lower lip		
		☐ Mucosa of lower lip		
		☐ Nasal cavity, NOS		
		☐ Nasal floor		
		☐ Nasal lateral wall		
		☐ Nasal septum		
		☐ Nasal vestibule		
		☐ Nasopharyngeal tonsils (adenoids)		
		☐ Palatine tonsil		
		☐ Paranasal sinus(es), ethmoid		
		Paranasal sinus(es), frontal		
		Paranasal sinus(es), maxillary		
		Paranasal sinus(es), sphenoid		
		Parotid gland, deep lobe		
		Parotid gland, superficial lobe		
		☐ Parotid gland, total ☐ Pharyngeal wall (posterior and/or lateral)		
		☐ Pharyngeal wall (posterior and/or lateral) ☐ Pharyngeal wall (posterior)		
		☐ Piriform sinus		
		□ Postcricoid		
		☐ Posterior commissure of glottis		
		☐ Retromolar area		
		☐ Skin		
		☐ Soft palate		
		☐ Subglottis		
		☐ Sublingual gland		
		☐ Submandibular gland		<u> </u>
		<u> </u>		

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	Enrollment: Head and Neck	
Tissue Source Site (TSS) Name:	HCMI Identifier (ID3):	
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	☐ True vocal cord	

		☐ True vocal cord☐ Upper gingiva			
		☐ Uvula			
		☐ Ventral surface of	ftongue		
		☐ Vestibule of mout			
		☐ Vestibule of mout			
		☐ Other (specify)	···, ······,		
176a	Other metastatic/	(-		6587395	If not included in the previous list,
	recurrent site				specify the site from which the
					metastatic/recurrent tissue used to
					develop the model was derived.
177	Site of relapse	☐ Local		2002506	If the primary tumor relapsed,
1,,	Site of Felapse	☐ Regional		2002300	provide the site of relapse.
		☐ Distant			provide the site of relapse.
		☐ Not applicable			
178	ICD-10 code			3226287	Provide the ICD-10 code for the
					metastatic/recurrent tumor used to
					generate the model submitted to
					HCMI.
179	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.
180	Maintenance and/or			6119066	Provide the name(s) of the
	consolidation therapy				maintenance and/or consolidation
	administered prior to				therapy administered to the patient
	collection of metastatic/				prior to the collection of the
	recurrent tissue				metastatic/recurrent tissue used to
181	Days to start of			5102411	develop the model.
101	Days to start of maintenance and/or			5102411	Provide the number of days from the index date to the date
	consolidation therapy				maintenance and/or consolidation
	from index date				therapy started.
182	Days to last known			5102431	Provide the number of days from
102	administration date of			3102 131	the index date to the last known
	maintenance and/or				date of maintenance and/or
	consolidation therapy				consolidation therapy.
	from index date				
183	Is the patient still	☐ Yes		6379568	Indicate whether the patient is still
	receiving treatment?	□ No			undergoing maintenance and/or
		☐ Unknown			consolidation therapy.
184	Disease status	☐ No evidence of di		2188290	Provide the disease status following
		☐ Progressive disea	se		maintenance and/or consolidation
		☐ Stable disease			therapy.
D	Investigation for the second	Unknown			
		es for Metastatic/Recu 	rrent Tumor Prognosis or Res	1	
185	Tumor laterality	☐ Right	☐ Midline	827	For a tumor in a paired organ, designate the side of the body on
		☐ Left	☐ Not specified		which the tumor or cancer
		☐ Bilateral	□ Not a paired site		developed.
186	Lymphovascular invasion	☐ Yes		64727	Indicate whether large vessel
100	present?	□ No		01,2,	(vascular) invasion or small, thin-
	p. 555	☐ Indeterminate			walled (lymphatic) invasion was
		☐ Unknown			detected in the primary tumor.
187	Perineural invasion			64181	Indicate whether perineural
	present?	Yes			invasion or infiltration of tumor or
		□ No □ Unknown			cancer is present.
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188	Question	Question Text	Data Entry Options	CDE ID	Instruction Text
188	188	Number of positive		89	Provide the number of lymph nodes
tested		lymph nodes			with disease involvement.
tested					
Extranodal extension	189	Number of lymph nodes		3	Provide the total number of lymph
Pesent   Abbent   Present   Abbent		tested			nodes tested for the presence of
Absent					cancer cells.
Unknown   G690713   Indicate whether or not immunohistochemical analysis for a pL6/CDKN2A mutation was performed. Personal place of the positive place of the positive place of the place	190	Extranodal extension	☐ Present	65043	Indicate whether extranodal
191   Was p16 HC performed?     Yes			☐ Absent		extension of the cancer is present.
Yes			☐ Unknown		
Paramasol Sinuses and Nasol Cavity Cancer-specific Questions   Performed, proceed to Question 193, otherwise, skip to Question 194, otherwise, skip to Question 194, otherwise, skip to Question 195, otherwise, skip to Question 198, otherwise, skip to Question 199, otherwise, skip to Question 199	191	Was p16 IHC performed?		6690713	
No			□ Yes		•
Persistive   Positive   Positive   Present   Present   Not identified   Present   Indicate whether a transglottic extension of the patient's laryngeal tumor was present.    Paranasal Sinuses and Nasal Cavity Cancer-specific Questions   Present   Present   Not identified   Present   Not id					į, -
192   p16 expression by IHC   Positive   Regative   R			☐ Unknown		
Positive   Regative					
Negative   Equivocal   Indicate whether a transglottic extension of the patient's laryngeal tumor was present.	102	n16 overession by IIIC	□ Dositivo	6600724	• •
Equivocal   Equivocal   Using immunohistochemistry.	192	pro expression by Inc		0090724	
Transglottic extension   Present   Not identified   Present   Not identified   Not identi					
Transglottic extension   Present   Not identified   Not id	Laruny Car	cer-specific Questions	L Equivocal		using initialionistochemistry.
Present Not identified extension of the patient's laryngeal tumor was present.    Paranosal Sinuses and Nasal Cavity Cancer-specific Questions				6788023	Indicate whether a transglottic
Not centified   Not centifie	193	Transgiottic extension	☐ Present	0708023	_
Paranasal Sinuses and Nasal Cavity Cancer-specific Questions   194			☐ Not identified		
Was NUT IHC   Performed?   Yes   No   No   Was NUT was performed.   Yes   No   Unknown   Positive   Positive	Paranasal	Sinuses and Nasal Cavity Ca	ncer-specific Questions		tumor was present.
performed?			neer-specific Questions	6788024	Indicate whether NUTM1 protein
No	134		_	0700024	-
Duknown   Duknown   Derformed   Note: If NUT IHC was performed, proceed to Question 195, otherwise, skip to Question 195.   195		performed.			· ·
Disknown   Performed, proceed to Question 195, otherwise, skip to Question 195.					* * * *
NUT expression by IHC			□ Unknown		•
Negative   Equivocal   Protein expression using immunohistochemistry.					
Equivocal   Immunohistochemistry.   Immunohistochemistry.   Indicate whether an analysis for translocation in the NUTM1 gene was performed?   Yes   No   Unknown   Ves   Ves	195	NUT expression by IHC	☐ Positive	6788028	Indicate the status of the NUTM1
196    Was NUT translocation analysis performed?   Yes			☐ Negative		protein expression using
analysis performed?			☐ Equivocal		immunohistochemistry.
No	196	Was NUT translocation		6788032	
Unknown   translocation analysis was performed, proceed to Question 197, otherwise, skip to Question 199.		analysis performed?	□ Yes		translocation in the NUTM1 gene
197   Was a NUT translocation identified?   Yes   Indicate whether a NUTM1   Chromosomal translocation was identified. Note: If a NUT translocation was identified, proceed to Question 199.			□ No		-
Skip to Question 199.   Skip to Question 199.   Indicate whether a NUTM1 chromosomal translocation was identified. Note: If a NUT translocation was identified. Note: If a NUT translocation was identified, proceed to Question 198, otherwise, skip to Question 199.			☐ Unknown		
197 Was a NUT translocation identified?  198 If translocation identified with NUT, which one?  198 Specify other NUT translocation  199 Was INI-1 IHC performed?  199 Was INI-1 IHC performed?  197 Yes  198 No  198 No  198 Specify other NUT translocation (specify)  199 Was INI-1 IHC performed?  190 Was INI-1 IHC performed?					=
identified?  Yes No No Chromosomal translocation was identified. Note: If a NUT translocation was identified. Note: If a NUT translocation was identified, proceed to Question 198, otherwise, skip to Question 199.  198 If translocation identified with NUT, which one? NUT-BRD4 Other translocation (specify)  Select the translocation identified with the NUTM1 gene. Note: If the NUT translocation is not listed, proceed to Question 198a, otherwise, skip to Question 199.  Specify other NUT translocation  For 88055 If not included in the previous list, provide the translocation identified with the NUTM1 gene.  Was INI-1 IHC performed?  Yes No No Unknown  Note: If INI-1 IHC was performed, proceed to Question 200, otherwise, skip to	107	Was a NUT translocation		6700020	-
identified. Note: If a NUT translocation was identified, proceed to Question 198, otherwise, skip to Question 199.  198	197			0700030	
was identified, proceed to Question 198, otherwise, skip to Question 199.  198		identified:			
198 If translocation identified with NUT, which one?			□ No		=
with NUT, which one?  NUT-BRD4 Other translocation (specify)  Specify other NUT translocation  Specify other NUT translocation  Specify other NUT translocation  With the NUTM1 gene. Note: If the NUT translocation is not listed, proceed to Question 199.  If not included in the previous list, provide the translocation identified with the NUTM1 gene.  6788025  Indicate whether INI-1 (SMARCB1) protein expression by immunohistochemistry (IHC) analysis was performed. Note: If INI-1 IHC was performed, proceed to Question 200, otherwise, skip to					
NUT translocation is not listed, proceed to Question 198a, otherwise, skip to Question 199.  198a Specify other NUT translocation  Specify other NUT translocation  199 Was INI-1 IHC performed?  Yes	198	If translocation identified		6788044	Select the translocation identified
Other translocation (specify)  Specify other NUT translocation  Specify other NUT translocation  Was INI-1 IHC performed?  Yes Specify other Num INI (SMARCB1) protein expression by immunohistochemistry (IHC) analysis was performed. Note: If INI-1 IHC was performed, proceed to Question 200, otherwise, skip to		with NUT, which one?	□ NUT-BRD4		with the NUTM1 gene. Note: If the
198a Specify other NUT translocation  199 Was INI-1 IHC performed?  199 Yes No Unknown  190 Was INI-1 IHC analysis was performed. Note: If INI-1 IHC was performed, proceed to Question 200, otherwise, skip to					• •
Specify other NUT translocation  198			= other translocation (specify)		
translocation  provide the translocation identified with the NUTM1 gene.  199 Was INI-1 IHC performed?    Yes	100-	Consideration AULT		6700055	
with the NUTM1 gene.  199 Was INI-1 IHC performed?  Yes No Unknown  with the NUTM1 gene.  6788025 Indicate whether INI-1 (SMARCB1) protein expression by immunohistochemistry (IHC) analysis was performed. Note: If INI-1 IHC was performed, proceed to Question 200, otherwise, skip to	1989			6/88055	-
199 Was INI-1 IHC performed?  ☐ Yes ☐ No ☐ Unknown  ☐ Was INI-1 IHC performed?  ☐ Yes ☐ No ☐ Unknown  ☐ G788025 Indicate whether INI-1 (SMARCB1) protein expression by immunohistochemistry (IHC) analysis was performed. Note: If INI-1 IHC was performed, proceed to Question 200, otherwise, skip to		transiocation			· ·
performed?  Yes  No Unknown  protein expression by immunohistochemistry (IHC) analysis was performed. Note: If INI-1 IHC was performed, proceed to Question 200, otherwise, skip to	100	Was INI 1 IHC		6700025	
immunohistochemistry (IHC) analysis was performed. Note: If INI-1 INO □ Unknown Unkno	199			6/88025	•
☐ Yes analysis was performed. Note: If INI-1 ☐ No ☐ Unknown ☐ Unknown ☐ Unknown ☐ Unknown ☐ Unknown		periorilleur			
□ No □ Unknown			□ Yes		* * * *
☐ Unknown Question 200, otherwise, skip to					

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
200	INI-1 expression by IHC	□ Positive	6788029	Indicate the status of the INI-1
		□ Negative		(SMARCB1) protein expression using
204	M DAV2 +	☐ Equivocal	6700022	immunohistochemistry.
201	Was PAX3 translocation	☐ Yes ☐ No	6788033	Indicate whether an analysis for
	analysis performed?	□ No □ Unknown		translocation in the PAX3 gene was performed. <i>Note: If PAX3 translocation</i>
		L Olikilowii		analysis was performed, proceed to
				Question 202, otherwise skip to
				question 204.
202	Was a PAX3	Yes	6788039	Indicate whether a PAX3
	translocation identified?	□ No		chromosomal translocation was
				identified. Note: If a PAX3 translocation was identified, proceed to
				Question 203, otherwise, skip to
				Question 204.
203	If translocation identified	☐ PAX3-MAML3	6788045	Select the translocation identified
	with PAX3, which one?	☐ Other translocation (specify)		with the PAX3 gene. Note: If the PAX3
				translocation is not listed, proceed to
				Question 203a, otherwise skip to Question 204.
203a	Specify other PAX3		6788050	If not included in the previous list,
	translocation			provide the translocation identified
		<del></del>		with the PAX3 gene.
204	Was EWSR1	☐ Yes	6788034	Indicate whether an analysis for
	translocation analysis	□ No		translocation in the EWSR1 gene
	performed?	☐ Unknown		was performed. Note: If EWSR1
				translocation analysis was performed,
				proceed to Question 205, otherwise, skip to Question 207.
205	Was an EWSR1	☐ Yes	6788040	Indicate whether an EWSR1
	translocation identified?	□ No		chromosomal translocation was
				identified. Note: If an EWSR1
				translocation was identified, proceed to
				Question 206, otherwise, skip to Question 207.
206	If translocation identified	☐ EWSR1-ATF1	6788046	Select the translocation identified
200	with EWSR1, which one?	☐ Other translocation	0700040	with the EWSR1 gene. <b>Note: If the</b>
	, , , , , , , , , , , , , , , , , , , ,			EWSR1 translocation is not listed,
				proceed to Question 206a,
				otherwise skip to Question 207.
206a	Specify other EWSR1		6788051	If not included in the previous list,
	translocation			provide the translocation identified
				with the EWSR1 gene.
207	Was ETV6 translocation	Yes	6788035	Indicate whether an analysis for
	analysis performed?	□ No □ Unknown		translocation in the ETV6 gene was performed. <i>Note: If ETV6 translocation</i>
		LI OTIKTIOWIT		analysis was performed, proceed to
				Question 208, otherwise, skip to
				Question 210.
208	Was an ETV6	□ Yes	6788041	Indicate whether an ETV6
	translocation identified?	□ No		chromosomal translocation was
				identified. Note: If an ETV6 translocation was identified, proceed to
				Question 209, otherwise, skip to
				Question 210.
209	If translocation identified	☐ ETV6-NTRK3	6788047	Select the translocation identified
	with ETV6, which one?	☐ Other translocation (specify)		with the ETV6 gene. Note: If the ETV6
				translocation is not listed, proceed to
				Question 209a, otherwise skip to Question 210.
				Question 210.
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
209a	Specify other ETV6		6788052	If not included in the previous list,
	translocation			provide the translocation identified
		<del></del>		with the ETV6 gene.
210	Was MAML2		6788036	Indicate whether an analysis for
	translocation analysis	□ Yes		translocation in the MAML2 gene
	performed?	□ No		was performed. Note: If MAML2
		☐ Unknown		translocation analysis was performed,
				proceed to Question 211, otherwise,
211	Was a MAML2		6788042	skip to Question 213.
211	translocation identified?		6788042	Indicate whether a MAML2 chromosomal translocation was
	translocation identified:	□ Yes		identified. Note: If a MAML2
		□ No		translocation was identified, proceed to
				Question 212, otherwise, skip to
				Question 213.
212	If translocation identified		6788048	Select the translocation identified
	with MAML2, which one?	☐ MAML2-CRTC1		with the MAML2 gene. Note: If the
		☐ MAML2-CRTC3		MAML2 translocation is not listed,
		☐ Other translocation (specify)		proceed to Question 212a, otherwise, skip to Question 213.
212a	Specify other MAML2		6788053	If not included in the previous list,
2120	translocation		0700033	provide the translocation identified
	transiocation	<del></del>		with the MAML2 gene.
213	Was MYB IHC		6788026	Indicate whether MYB protein
	performed?	□ V	0,00020	expression by immunohisto-
		☐ Yes		chemistry (IHC) analysis was
		☐ No ☐ Unknown		performed. Note: If MYB IHC was
		LI UNKNOWN		performed, proceed to Question 214,
				otherwise, skip to Question 215.
214	MYB expression by IHC	☐ Positive	6788030	Indicate the status of the MYB
		□ Negative		protein expression using
_		☐ Equivocal		immunohistochemistry.
215	Was MYB translocation		6788037	Indicate whether an analysis for
	analysis performed?	☐ Yes		translocation in the MYB gene was
		□ No		performed. Note: If MYB translocation analysis was performed, proceed to
		☐ Unknown		Question 216, otherwise, skip to
				Question 218.
216	Was a MYB translocation		6788043	Indicate whether a MYB
	identified?	□ Yes		chromosomal translocation was
		□ No		identified. Note: If a MYB translocation
				was identified, proceed to Question 217,
247	If horsels and an interest in		6700040	otherwise, skip to Question 218.
217	If translocation identified		6788049	Select the translocation identified
	with MYB, which one?	☐ MYB-NFIB		with the MYB gene. Note: If the MYB translocation is not listed, proceed to
		☐ Other translocation (specify)		Question 217a, otherwise, skip to
				Question 218.
217a	Specify other MYB		6788054	If not included in the previous list,
	translocation			provide the translocation identified
		<del></del>		with the MYB gene.
218	Was HER2 IHC		6063454	Indicate whether HER2 expression
	performed?	□ Yes		was assessed by immunohisto-
		□ No		chemistry (IHC). Note: If HER2 IHC was
		☐ Unknown		performed, proceed to Question 219,
				otherwise, skip to Question 220.
219	HER2 expression by IHC		2957563	Indicate the expression of HER2 as
213	TIENZ CAPICSSION BY INC	☐ Positive	2937303	assessed by immunohistochemistry
		□ Negative		(IHC).
		☐ Equivocal		\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
220	Was HER2 FISH/CISH		6063447	Indicate whether HER2 was assessed
	performed?	☐ Yes ☐ No ☐ Unknown		by fluorescence in situ hybridization (FISH) or chromogenic in situ hybridization (CISH). Note: If HER2 FISH/CISH was performed, proceed to Question 221, otherwise, skip to Question 226.
221	HER2 status by FISH/CISH	☐ Amplified ☐ Not amplified	2854089	Select the HER2 status as assessed by FISH/CISH.
222	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.
223	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.
224	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.
225	HER2/neu chromosome 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.
226	Was Androgen Receptor IHC performed?	☐ Yes ☐ No ☐ Unknown	6788027	Indicate whether Androgen Receptor expression was assessed by immunohistochemistry (IHC). Note: If androgen receptor IHC was performed, proceed to Question 227, otherwise, skip to Question 228.
227	Androgen Receptor expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6788031	Indicate the expression of Androgen Receptor as assessed by immunohistochemistry (IHC).
Additional	Metastatic/Recurrent Tumo	or Biospecimen Information (if applicable)	<u>'</u>	, ,
228	Are you submitting an additional metastatic/ recurrent tumor tissue sample?	☐ Yes ☐ No		A biospecimen obtained from a single site at a single timepoint in progression that is portioned for both sequencing and model generation counts as 1 single tumor specimen. A biospecimen obtained from another site or at a later timepoint in progression that is portioned for both sequencing and model generation counts as a second single tumor specimen. Note: If yes, proceed to Question 229, otherwise, skip to Question 246.
229	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.
230	CMDC tissue ID		6586035	Please provide the CMDC sample ID for this biospecimen as it will appear on tubes and the Sample Submission Form transmitted to the BPC.

# **Enrollment: Head and Neck**

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
231	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.
232	Head and neck cancer region	<ul> <li>□ Lip and oral cavity</li> <li>□ Pharynx</li> <li>□ Larynx</li> <li>□ Paranasal sinuses and nasal cavity</li> <li>□ Salivary glands</li> </ul>	2179718	Select the anatomic site of origin for the head and neck cancer in the patient.
233	Metastatic/recurrent tumor tissue sample preservation method	☐ Cryopreserved ☐ FFPE ☐ Frozen ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the metastatic/recurrent tumor tissue sample collected for molecular characterization.
234	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.
235	Method of metastatic/ recurrent cancer sample procurement	□ Buccal mucosal resection □ Endolaryngeal excision □ Excision □ Glossectomy □ Incisional biopsy □ Laryngopharyngectomy □ Mandibulectomy □ Maxillectomy □ Metastasectomy □ Neck (lymph node) dissection □ Palatectomy □ Parotidectomy, deep □ Parotidectomy, not specified □ Parotidectomy, superficial □ Parotidectomy, total □ Partial laryngectomy □ Partial maxillectomy □ Radical maxillectomy □ Resection, submandibular gland □ Resection, submandibular gland □ Supracricoid laryngectomy □ Supraglottic laryngectomy □ Tonsillectomy □ Total laryngectomy □ Transoral laser excision (glottis) □ Vertical hemilaryngectomy □ Other Method (specify)	6587389	Indicate the procedure performed to obtain the metastatic/recurrent tumor tissue. Note: If the method of procurement is not listed, proceed to Question 235a, otherwise, skip to Question 236.
235a	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.
236	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.
				Page <b>27</b> of <b>25</b>

# **Enrollment: Head and Neck**

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
237	Metastatic/recurrent site	☐ Alveolar process, mandibular	6587394	Select the site from which the
		☐ Alveolar process, maxillary		metastatic/recurrent tissue used to
		☐ Anterior commissure of glottis		develop the model was derived.
		☐ Anterior floor of mouth		Note: If the metastatic/recurrent site is
		☐ Anterior two-thirds of tongue		not listed, proceed to Question 237a, otherwise, skip to Question 238.
		☐ Aryepiglottic folds		otherwise, skip to Question 238.
		Arytenoid(s)		
		Base of tongue, including lingual tonsil		
		☐ Bone ☐ Bone marrow		
		☐ Bone marrow ☐ Buccal mucosa		
		☐ Commissure of lip		
		☐ Dorsal surface of tongue		
		☐ Epiglottis, laryngeal aspect		
		☐ Epiglottis, lingual aspect		
		☐ External lower lip		
		☐ External upper lip		
		☐ False vocal cord		
		☐ Floor of mouth		
		☐ Glottis, with subglottic extension		
		☐ Hard palate		
		☐ Larynx ventricle		
		☐ Lateral border of tongue		
		Liver		
		☐ Lower gingiva		
		Lung		
		Lymph node(s), non-regional		
		Lymph node(s), regional		
		☐ Mandible		
		☐ Maxilla		
		☐ Mediastinum		
		☐ Minor gland(s) ☐ Mucosa of lower lip		
		☐ Mucosa of lower lip		
		☐ Nasal cavity, NOS		
		☐ Nasal floor		
		☐ Nasal lateral wall		
		☐ Nasal septum		
		☐ Nasal vestibule		
		☐ Nasopharyngeal tonsils (adenoids)		
		☐ Palatine tonsil		
		☐ Paranasal sinus(es), ethmoid		
		☐ Paranasal sinus(es), frontal		
		Paranasal sinus(es), maxillary		
		Paranasal sinus(es), sphenoid		
		Parotid gland, deep lobe		
		Parotid gland, superficial lobe		
		Parotid gland, total		
		☐ Pharyngeal wall (posterior and/or lateral) ☐ Pharyngeal wall (posterior)		
		☐ Priaryngear wair (posterior) ☐ Piriform sinus		
		□ Postcricoid		
		☐ Posterior commissure of glottis		
		☐ Retromolar area		
		☐ Skin		
		☐ Soft palate		
		☐ Subglottis		
		☐ Sublingual gland		
		☐ Submandibular gland		
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	ce Site (TSS) Name: By:			
		☐ True vocal cord ☐ Upper gingiva ☐ Uvula ☐ Ventral surface of tongue ☐ Vestibule of mouth, mandibular ☐ Vestibule of mouth, maxillary ☐ Other (specify)		
237a	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.
238	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, provide the site of relapse.
239	ICD-10 code		3226287	Provide the ICD-10 code for the metastatic/recurrent tumor used to generate the model submitted to HCMI.
240	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.
241	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.
242	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.
243	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.
244	Is the patient still receiving treatment?	☐ Yes☐ No☐ Unknown	6379568	Indicate whether the patient is still undergoing maintenance and/or consolidation therapy.
245	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.
Responsiv metastatic,	reness to Treatment (Note: Qu /recurrent biospecimens.)	or Prognostic/Predictive/Lifestyle Features for Addit lestions 185-227 may be repeated to capture clinical molec		
	c/Recurrent Tumor Model In	formation	T -	
246	METASTATIC/ RECURRENT model biospecimen ordinal		6594587	Please provide a number to identify which biospecimen this is in the sequence. Note: The first biospecimen should be number "1," the second should be number "2," etc.

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
247	CMDC model ID		<del></del>	6586036	Please provide the CMDC model ID
					for this sample as it will appear
					on tubes and the Sample
					Submission Form transmitted to the
	I			a=c:::::	BPC.
248	BPC submitter ID (if			6584919	Please provide the BPC-generated ID
	available)				for this sample as it will appear on
					the Sample Submission Form
240	Madal's METACTATIC/			6586035	transmitted to the BPC.
249	Model's METASTATIC/ RECURRENT tumor tissue			0300033	Enter the CMDC Sample ID of the METASTATIC/RECURRENT tissue
	CMDC sample ID				from which this model is derived.
250	Model's METASTATIC/			6584266	Enter the biospecimen ordinal
230	RECURRENT tumor tissue			0304200	of the METASTATIC/RECURRENT
	biospecimen ordinal				tissue from which this model is
	and permitting the state of the				derived.
Additional	Metastatic/Recurrent Biosp	ecimen Tumor Model II	nformation (if applicable)		
251	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
252	0.450				should be number "2," etc.
252	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.
253	BPC submitter ID (if			6584919	Please provide the BPC-generated ID
255	•			0304919	for this sample as it will appear on
	available)				the Sample Submission Form
					transmitted to the BPC.
254	Model's METASTATIC/			6586035	Enter the CMDC Sample ID of the
	RECURRENT tumor tissue				METASTATIC/RECURRENT tissue
	CMDC sample ID				from which this model is derived.
255	Model's METASTATIC/			6584266	Enter the biospecimen ordinal of the
	RECURRENT tumor tissue				METASTATIC/RECURRENT tissue
	biospecimen ordinal				from which this model is derived.
Other Bios	pecimen Information				
256	Are you submitting an				Indicate whether an OTHER tissue
	OTHER tissue sample?	☐ Yes			sample (e.g. pre-malignant, non-
		□ No			malignant, or dysplastic tissue, etc.)
					was collected for HCMI for this case.
257	OTHER tissue			6584267	Note: If yes, proceed to Question 257.  Please provide a number to identify
257				0364207	which biospecimen this is in the
	biospecimen ordinal				sequence. Note: The first biospecimen
					should be number "1," the second
					should be number "2," etc.
258	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.
259	BPC submitter ID (if			6584919	Please provide the BPC-generated ID
	available)				for this sample as it will appear on
					the Sample Submission Form
266	OTHER #:			E 400501	transmitted to the BPC.
260	OTHER tissue sample	☐ Cryopreserved	□ ост	5432521	Provide the method used to
	preservation method	☐ FFPE			preserve the OTHER tissue sample collected for molecular
		☐ Frozen	☐ Snap frozen		characterization.
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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
261	Other method of cancer	☐ Buccal mucosal resection	6587398	Provide the procedure performed to
	sample procurement	<ul> <li>□ Core needle biopsy</li> <li>□ Endolaryngeal excision</li> <li>□ Excision</li> <li>□ Fine needle aspirate</li> <li>□ Glossectomy</li> </ul>		obtain the OTHER tissue. Note: If the method of procurement is not listed, proceed to Question 261a, otherwise, skip to Question 262.
		□ Incisional biopsy □ Laryngopharyngectomy □ Mandibulectomy □ Maxillectomy □ Neck (lymph node) dissection □ Palatectomy □ Parotidectomy, deep □ Parotidectomy, not specified □ Parotidectomy, superficial □ Parotidectomy, total □ Partial laryngectomy □ Partial maxillectomy □ Radical maxillectomy □ Resection, sublingual gland □ Resection, submandibular gland □ Supracricoid laryngectomy □ Supraglottic laryngectomy □ Tonsillectomy □ Total laryngectomy □ Total laryngectomy □ Transoral laser excision (glottis)		
		☐ Vertical hemilaryngectomy		
261a	Specify method of OTHER tissue sample procurement	Other (specify)	6587399	Specify the procedure performed to obtain the OTHER tissue.
262	Number of days from index date to date of OTHER sample procurement		3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
263	Tissue type	☐ Pre-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type.  Note: If the OTHER tissue type is not listed, proceed to Question 263a, otherwise, skip to Question 264.
263a	Specify tissue type		64785	Specify the OTHER tissue type if not in the provided list.
264	Anatomic site of OTHER tissue	□ Alveolar process, mandibular □ Alveolar process, maxillary □ Anterior commissure □ Anterior floor of mouth □ Anterior two-thirds of tongue □ Aryepiglottic folds □ Arytenoid(s) □ Base of tongue, including lingual tonsil □ Buccal mucosa □ Commissure of lip □ Dorsal surface of tongue □ Epiglottis, laryngeal aspect □ Epiglottis, lingual aspect □ External lower lip □ External upper lip □ False vocal cord	6696813	Select the site from which the OTHER tissue used to develop the model was derived. Note: If the OTHER tissue site is not listed, proceed to Question 264a, otherwise, skip to Question 265.

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sue Sour	rce Site (TSS) Name:			
	By:			
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		☐ Floor of mouth		
		☐ Glottis, with subglottic extension		
		☐ Hard palate		
		☐ Larynx ventricle		
		☐ Lateral border of tongue		
		☐ Lower gingiva☐ Mandible		
		☐ Maxilla		
		☐ Mucosa of lower lip		
		☐ Mucosa of upper lip		
		☐ Nasal cavity, NOS		
		□ Nasal floor		
		□ Nasal lateral wall		
		□ Nasal septum		
		☐ Nasal vestibule		
		☐ Nasopharyngeal tonsils (adenoids)		
		☐ Palatine tonsil		
		☐ Paranasal sinus(es), ethmoid		
		☐ Paranasal sinus(es), frontal		
		☐ Paranasal sinus(es), maxillary		
		☐ Paranasal sinus(es), sphenoid		
		Parotid gland, deep lobe		
		Parotid gland, superficial lobe		
		☐ Parotid gland, total		
		☐ Pharyngeal wall (posterior and/or lateral)		
		☐ Pharyngeal wall (posterior)		
		☐ Piriform sinus ☐ Postcricoid		
		☐ Posterior commissure		
		☐ Retromolar area		
		☐ Soft palate		
		☐ Subglottis		
		☐ Sublingual gland		
		☐ Submandibular gland		
		☐ True vocal cord		
		☐ Upper gingiva		
		☐ Uvula		
		☐ Ventral surface of tongue		
		☐ Vestibule of mouth, mandibular		
		☐ Vestibule of mouth, maxillary		
		☐ Other (specify)		
264a	Specify anatomic site of		6584916	Specify the site of OTHER tissue, if
	OTHER tissue			not in the previous list.
265	ICD 40 c 1 -		222622	Dravida tha ICD 40 and 10 at
265	ICD-10 code		3226287	Provide the ICD-10 code for the
				OTHER tissue used to generate the
360	ICD O 2 histology and		2226275	model submitted to HCMI.
266	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.
Addition	□ al OTHER biospecimen Inform	nation (if applicable)	1	der sabilited to Helvii.
267	Are you submitting an	O FF ··· · · · ·		Indicate whether an additional
	additional OTHER tissue			OTHER tissue sample (pre-
	sample?			malignant, non-malignant, or
	•	☐ Yes		dysplastic tissue, etc.) is being
		□ No		submitted for HCMI for this case.
				Note: If yes, proceed to Question 268,

otherwise, skip to Question 278.

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
268	OTHER tissue biospecimen ordinal		6584267	Please provide a number to identify which biospecimen this is in the sequence. Note: The first biospecimen should be number "1," the second should be number "2," etc.
269	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.
270	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.
271	OTHER tissue sample preservation method	☐ Cryopreserved ☐ OCT ☐ FFPE ☐ Snap frozen	5432521	Provide the method used to preserve the OTHER tissue sample collected for molecular characterization.
272	Other method of cancer sample procurement	□ Buccal mucosal resection □ Core needle biopsy □ Endolaryngeal excision □ Excision □ Fine needle aspirate □ Glossectomy □ Incisional biopsy □ Laryngopharyngectomy □ Mandibulectomy □ Maxillectomy □ Neck (lymph node) dissection □ Palatectomy □ Parotidectomy, deep □ Parotidectomy, not specified □ Parotidectomy, superficial □ Partial laryngectomy □ Partial maxillectomy □ Resection, sublingual gland □ Resection, submandibular gland □ Supracricoid laryngectomy □ Supraglottic laryngectomy □ Tonsillectomy □ Total laryngectomy □ Transoral laser excision (glottis) □ Vertical hemilaryngectomy □ Other (specify)	6587398	Provide the procedure performed to obtain the OTHER tissue. Note: If the method of procurement is not listed, proceed to Question 272a, otherwise, skip to Question 273.
272a	Specify method of OTHER tissue sample procurement		6587399	Specify the procedure performed to obtain the OTHER tissue.
273	Number of days from index date to date of OTHER sample procurement		3288495	Provide the number of days from the index date to the date of the procedure that produced the OTHER tissue submitted for HCMI.
274	Tissue type	☐ Pre-malignant ☐ Other (specify)	64784	Indicate the OTHER tissue type.  Note: If the OTHER tissue type is not listed, proceed to Question 274a, otherwise, skip to Question 275.
274a	Specify tissue type		64785	Specify the OTHER tissue type if not in the provided list.

# **Enrollment: Head and Neck**

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
275	Anatomic site of OTHER	☐ Alveolar process, mandibular	6696813	Select the site from which the
	tissue	☐ Alveolar process, maxillary		OTHER tissue used to develop the
		☐ Anterior commissure		model was derived. Note: If the
		☐ Anterior floor of mouth		OTHER tissue site is not listed, proceed
		☐ Anterior two-thirds of tongue		to Question 275a, otherwise, skip to
		☐ Aryepiglottic folds		Question 276.
		☐ Arytenoid(s)		
		☐ Base of tongue, including lingual tonsil		
		☐ Buccal mucosa		
		☐ Commissure of lip		
		☐ Dorsal surface of tongue		
		Epiglottis, laryngeal aspect		
		Epiglottis, lingual aspect		
		☐ External lower lip		
		☐ External upper lip		
		☐ False vocal cord		
		☐ Floor of mouth		
		☐ Glottis, with subglottic extension		
		Hard palate		
		☐ Larynx ventricle		
		☐ Lateral border of tongue		
		☐ Lower gingiva☐ Mandible		
		☐ Maxilla		
		☐ Mucosa of lower lip		
		Mucosa of lower lip     Mucosa of upper lip		
		☐ Nasal cavity, NOS		
		☐ Nasal floor		
		☐ Nasal lateral wall		
		☐ Nasal septum		
		☐ Nasal vestibule		
		☐ Nasopharyngeal tonsils (adenoids)		
		☐ Palatine tonsil		
		☐ Paranasal sinus(es), ethmoid		
		☐ Paranasal sinus(es), frontal		
		☐ Paranasal sinus(es), maxillary		
		☐ Paranasal sinus(es), sphenoid		
		☐ Parotid gland, deep lobe		
		☐ Parotid gland, superficial lobe		
		☐ Parotid gland, total		
		☐ Pharyngeal wall (posterior and/or lateral)		
		☐ Pharyngeal wall (posterior)		
		☐ Piriform sinus		
		☐ Postcricoid		
		☐ Posterior commissure		
		☐ Retromolar area		
		☐ Soft palate		
		☐ Subglottis		
		☐ Sublingual gland		
		☐ Submandibular gland		
		☐ True vocal cord		
		☐ Upper gingiva		
		□ Uvula		
		☐ Ventral surface of tongue		
		☐ Vestibule of mouth, mandibular		
		☐ Vestibule of mouth, maxillary		
		☐ Other (specify)		
275a	Specify anatomic site of		6584916	Specify the site of OTHER tissue, if
	OTHER tissue			not in the previous list.

286

287

Model's OTHER tissue

Model's OTHER tissue

biospecimen ordinal

CMDC sample ID

#### **Enrollment: Head and Neck**

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Tissue Source Site (TSS) Name:	HCMI Identifier (ID3):	<b>1</b> 695	Trans.
Completed By:	Completion Date (MM/DD/YYYY):	a b	

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
276	ICD-10 code		3226287	Provide the ICD-10 code for the OTHER tissue used to generate the
277	ICD-O-3 histology code		3226275	model submitted to HCMI.  Provide the ICD-O-3 histology code describing the morphology of the OTHER tissue used to generate the model submitted to HCMI.
Other Tiss	ue Model Information			
278	OTHER tissue model biospecimen ordinal		6594590	Please provide a number to identify which biospecimen this is in the sequence. Note: The first biospecimen should be number "1," the second should be number "2," etc.
279	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.
280	BPC submitter ID (if available)		6584919	Please provide the BPC-generated for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
281	Model's OTHER tissue CMDC sample ID		6586035	Enter the CMDC Sample ID of the OTHER tissue from which this modis derived.
282	Model's OTHER tissue biospecimen ordinal		6584267	Enter the biospecimen ordinal of the OTHER tissue from which this mode is derived.
Additional	Other Tissue Model Inform	nation (if applicable)	<b>,</b>	
283	OTHER tissue model biospecimen ordinal		6594590	Please provide a number to identify which biospecimen this is in the sequence. Note: The first biospecimen should be number "1," the second should be number "2," etc.
284	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.
285	BPC submitter ID (if available)		6584919	Please provide the BPC-generated for this sample as it will appear on the Sample Submission Form transmitted to the BPC.
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6586035

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Enter the CMDC Sample ID of the

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