Follow-Up: Head and Neck

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

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

Form Notes: A Follow-Up Form should be completed for each HCMI case upon notice of model establishment and molecular characterization success from Leidos. All information provided on this form should include activity from the "Date of Last Contact" provided on the HCMI Enrollment Form to the most recent date of contact with the patient or the patient's medical record.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	☐ Initial pathologic diagnosis ☐ Sample procurement ☐ First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.
Follow-Up Patient Status				
4	Number of days from index date to date of last follow-up	_____	3008273	Provide the number of days from the index date to the last date of follow-up with the patient or last contact with the medical record.
5	Vital status	☐ Alive ☐ Dead ☐ Lost to follow-up	5	Indicate whether the patient is alive, dead, or lost to follow-up at the date of last contact. ***Note: If the patient is deceased, continue to Question 6, otherwise skip to Question 8.***
6	Number of days from index date to date of death	_____	3165475	Provide the number of days from the index date to the date of death.
7	Cause of death	☐ Related to this cancer ☐ Non-cancer related ☐ Related to another cancer ☐ Other (specify) ☐ Unknown	2554674	Indicate the patient's cause of death.
7a	Other cause of death	_____	4783275	If the cause of death is not included in the provided list, specify the cause of death.
8	Disease status at follow-up	☐ No evidence of disease ☐ Stable disease ☐ Progressive disease ☐ Unknown	2188290	Provide the last known state of the patient's tumor up to the point of current follow-up data submission.
Treatment Information				
9	Was surgery performed as part of the primary disease treatment plan?	☐ Yes ☐ No ☐ Unknown	2978013	Indicate whether surgery was performed to treat the primary tumor. ***Note: If the patient did not receive surgical treatment, skip to Question 11.***
10	Number of days from index date to date of surgical treatment	_____	3008335	Provide the number of days from the index date to the date of surgical treatment.
11	Was systemic adjuvant therapy administered?	☐ Yes ☐ No ☐ Unknown	3397567	Indicate whether the patient received systemic adjuvant pharmaceutical therapy. ***Note: If the patient did have systemic adjuvant therapy, the Pharmaceutical Supplemental Form should be completed.***
12	Was adjuvant radiation therapy administered?	☐ Yes ☐ No ☐ Unknown	2005312	Indicate whether the patient had adjuvant radiation therapy. ***Note: If the patient had adjuvant radiation therapy, the Radiation Supplemental Form should be completed.***

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Pharmaceutical Supplemental Form

Form Notes: A Pharmaceutical Supplemental Form should be completed for each HCMI case for which the patient received adjuvant pharmaceutical therapy. All information provided on this form should include activity from the "Date of Last Contact" provided on the HCMI Enrollment Form to the most recent date of contact with the patient or the patient's medical record.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	Was cytotoxic chemotherapy administered?	☐ Yes ☐ No ☐ Unknown	5628399	Indicate whether the patient received cytotoxic chemotherapy. ***Note: If cytotoxic chemotherapy was administered, proceed to the "Cytotoxic Chemotherapy" section, Questions 5-8.***
2	Was immunotherapy (cellular and immune checkpoint) administered?	☐ Yes ☐ No ☐ Unknown	3057655	Indicate whether the patient received immunotherapy. ***Note: If immunotherapy was administered, proceed to the "Immunotherapy" section, Questions 9-12.***
3	Was targeted therapy (small molecule inhibitors and targeted antibodies) administered?	☐ Yes ☐ No ☐ Unknown	2785850	Indicate whether the patient received targeted therapy. ***Note: If targeted therapy was administered, proceed to the "Targeted Therapy" section, Questions 13-16.***
4	Was hormone therapy administered?	☐ Yes ☐ No ☐ Unknown	6385020	Indicate whether the patient received hormone therapy. ***Note: If hormone therapy was administered, proceed to the "Hormone Therapy" section, Questions 17-21***
Cytotoxic Chemotherapy				
5	Chemotherapeutic administered	☐ Cisplatin ☐ Carboplatin ☐ Docetaxel ☐ Methotrexate ☐ Carboplatin and Paclitaxel ☐ Cisplatin (Carboplatin) and Paclitaxel ☐ Cisplatin (Carboplatin) and Fluorouracil ☐ Cisplatin (Carboplatin) and Pemetrexed ☐ Carboplatin (Cisplatin), Fluorouracil and Cetuximab ☐ Gemcitabine and Paclitaxel ☐ Carboplatin (Cisplatin), Fluorouracil, and Pembrolizumab ☐ Other (specify)	2853873	Select the chemotherapeutic(s) used for therapy. ***Note: Questions 5-8 are repeatable as needed to capture each individual chemotherapeutic administered. If the chemotherapeutic is not included in the provided list, proceed to Question 5a, otherwise, skip to Question 6.***
5a	Other chemotherapeutic	_____	2514640	If the adjuvant therapy is not included in the provided list, specify adjuvant therapy.
6	Days from index date to start of pharmaceutical treatment	_____	5102411	Provide the number of days from the index date to the date of initiation of treatment with adjuvant pharmaceutical therapy.
7	Days from index date to last known date of pharmaceutical treatment	_____	65167	Provide the number of days from the index date to the last known date of pharmaceutical treatment.
8	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing treatment.

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Immunotherapy				
9	Immunotherapy administered	☐ Pembrolizumab ☐ Nivolumab ☐ Cemiplimab ☐ Durvalumab ☐ Ipilimumab ☐ Tremelimumab ☐ Pembrolizumab plus Ipilimumab ☐ Durvalumab plus Tremelimumab ☐ Other (specify)	6788001	Select the immunotherapeutic(s) used for therapy.
9a	Other Immunotherapy administered	_____	2953828	If the immunotherapy is not included in the provided list, specify the immunotherapy. ***Note: Questions 9-12 are repeatable as needed to capture each individual immunotherapy administered. If the immunotherapy is not listed, proceed to Question 9a, otherwise, skip to Question 10.***
10	Days from index date to start of immunotherapy treatment	_____	5102411	Provide the number of days from the index date to the date of the initiation of treatment with immunotherapy.
11	Days from index date to last known date of immunotherapy treatment	_____	65167	Provide the number of days from the index date to the last known date of immunotherapy treatment.
12	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing treatment.
Targeted Therapy				
13	Targeted therapy	☐ Cetuximab ☐ Cetuximab, Carboplatin (Cisplatin), Fluorouracil ☐ Cetuximab, Carboplatin, and Paclitaxel ☐ Bevacizumab ☐ Panitumumab ☐ Lenvatinib ☐ Afatinib ☐ Other (specify)	6788000	Select the targeted therapeutic(s) administered. ***Note: Questions 13-16 are repeatable as needed to capture each individual targeted therapy administered. If the targeted therapy is listed, proceed to Question 13a, otherwise, skip to Question 14.***
13a	Other targeted therapy	_____	4308476	If the targeted therapy is not included in the provided list, specify targeted therapy.
14	Days from index date to start of targeted therapy treatment	_____	5102411	Provide the number of days from the index date to the date of initiation of treatment with targeted therapy.
15	Days from index date to last known date of targeted therapy treatment	_____	65167	Provide the number of days from the index date to the last known date of targeted therapy treatment.
16	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing treatment.
Hormone Therapy				
17	Hormone therapy	☐ Herceptin ☐ Androgen deprivation (specify) ☐ Other (specify)	2582817	Select the hormone therapy administered to the patient. ***Note: Questions 17-21 are repeatable as needed to capture each individual targeted therapy administered. If the hormone therapy is not listed, proceed to Question 17a, otherwise, skip to Question 19. If the androgen deprivation was given, proceed to Question 18.***

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
17a	Other hormone therapy	_____	2405358	If the hormone therapy is not included in the provided list, specify hormone therapy.
18	Specify androgen therapy	_____	6942918	Specify the androgen deprivation therapies administered.
19	Days from index date to start of targeted therapy treatment	_____	5102411	Provide the number of days from the index date to the date of initiation of treatment with hormone therapy.
20	Days from index date to last known date of targeted therapy treatment	_____	65167	Provide the number of days from the index date to the last known date of hormone therapy treatment.
21	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing treatment.

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Radiation Supplemental Form

Form Notes: A Radiation Supplemental Form should be completed for each HCMI case for which the patient received adjuvant radiation therapy. All information provided on this form should include activity from the "Date of Last Contact" provided on the HCMI Enrollment Form to the most recent date of contact with the patient or the patient's medical record.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	Radiation therapy administered type	☐ 2D conventional ☐ 3D conformal ☐ Brachytherapy HDR ☐ Brachytherapy LDR ☐ IMRT ☐ Proton Beam ☐ Stereotactic Body RT ☐ Stereotactic Radiosurgery ☐ WBRT ☐ Other (specify) ☐ Unspecified	3028890	Provide the type of adjuvant radiation therapy that was administered to the patient, if not collected on the enrollment form for this patient. ***Note: If the radiation therapy type is not included in the provided list, proceed to Question 1a, otherwise, skip to Question 2.***
1a	Other radiation therapy	_____	3028890	If the radiation therapy type is not included in the provided list, specify the type.
2	Days from index date to start of adjuvant radiation therapy treatment	_____	5102411	Provide the number of days from the index date to the date of treatment with adjuvant post-operative radiation therapy.
3	Days from index date to last known date of adjuvant radiation therapy treatment	_____	65167	Provide the number of days from the index date to the last known date of radiation therapy treatment.
4	Is the patient still receiving treatment?	☐ Yes ☐ No ☐ Unknown	6379568	Indicate whether the patient is still undergoing treatment.