
# Follow-Up: Stomach

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<br>☐ Sample procurement<br>☐ 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<br>☐ Dead<br>☐ Lost to follow-up | 5 | Indicate whether the patient is alive, dead, or lost to follow-up at the date of last contact.<br>***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<br>☐ Non-cancer related<br>☐ Related to another cancer<br>☐ Other (specify)<br>☐ 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<br>☐ Stable disease<br>☐ Progressive disease<br>☐ 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<br>☐ No<br>☐ Unknown | 2978013 | Indicate whether surgery was performed to treat the primary tumor.<br>***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<br>☐ No<br>☐ Unknown | 3397567 | Indicate whether the patient received systemic adjuvant pharmaceutical therapy.<br>***Note: If the patient did have systemic adjuvant therapy, the Pharmaceutical Supplemental Form should be completed.*** |
| 12 | Was adjuvant radiation therapy administered? | ☐ Yes<br>☐ No<br>☐ Unknown | 2005312 | Indicate whether the patient had adjuvant radiation therapy.<br>***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<br>☐ No<br>☐ Unknown | 5628399 | Indicate whether the patient received cytotoxic chemotherapy.<br>***Note: If cytotoxic chemotherapy was administered, proceed to the "Cytotoxic Chemotherapy" section, Questions 2-5.*** |
| 2 | Was immunotherapy (cellular and immune checkpoint) administered? | ☐ Yes<br>☐ No<br>☐ Unknown | 3057655 | Indicate whether the patient received immunotherapy.<br>***Note: If immunotherapy was administered, proceed to the "Immunotherapy" section, Questions 6-9.*** |
| 3 | Was targeted therapy (small molecule inhibitors and targeted antibodies) administered? | ☐ Yes<br>☐ No<br>☐ Unknown | 2785850 | Indicate whether the patient received targeted therapy.<br>***Note: If targeted therapy was administered, proceed to the "Targeted Therapy" section, Questions 10-13.*** |
| ***Cytotoxic Chemotherapy*** | | | | |
| 2 | Chemotherapeutic administered | ☐ Carboplatin<br>☐ Cisplatin; 5-fluorouracil (5-FU) and Trastuzumab<br>☐ Docetaxel<br>☐ Epirubicin<br>☐ Epirubicin; Cisplatin; 5-fluorouracil (ECF)<br>☐ Epirubicin; Cisplatin; Capecitabine (ECX)<br>☐ Epirubicin; Oxaloplatin; Capecitabine (EOX)<br>☐ Irinotecan<br>☐ Oxaliplatin<br>☐ Paclitaxel<br>☐ Other (specify) | 2853873 | Select the chemotherapeutic used for therapy.<br>***Note: Questions 2-5 are repeatable as needed to capture each individual chemotherapeutic administered.***<br>***If the chemotherapeutic is not included in the provided list, proceed to Question 2a, otherwise, skip to Question 3.*** |
| 2a | Other chemotherapeutic | _____ | 2514640 | If the adjuvant therapy is not included in the provided list, specify adjuvant therapy. |
| 3 | 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. |
| 4 | 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. |
| 5 | Is the patient still receiving treatment? | ☐ Yes<br>☐ No<br>☐ Unknown | 6379568 | Indicate whether the patient is still undergoing treatment. |


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|---|---|---|---|---|
| ***Immunotherapy*** | | | | |
| 6 | Immunotherapy administered | _____ | 2185614 | Select the immunotherapy administered. ***Note: Questions 6-9 are repeatable as needed to capture each individual immunotherapy administered.*** |
| 7 | 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. |
| 8 | 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. |
| 9 | Is the patient still receiving treatment? | ☐ Yes<br>☐ No<br>☐ Unknown | 6379568 | Indicate whether the patient is still undergoing treatment. |
| ***Targeted Therapy*** | | | | |
| 10 | Targeted therapy administered | ☐ Ramucirumab<br>☐ Trastuzumab<br>☐ Other (specify) | 6270571 | Select the targeted therapy administered. ***Note: Questions 10-13 are repeatable as needed to capture each individual targeted therapy administered.*** ***If the targeted therapy is not included in the provided list, proceed to Question 10a, otherwise, skip to Question 11.*** |
| 10a | Other targeted therapy | _____ | 4308476 | If the targeted therapy is not included in the provided list, specify the therapy. |
| 11 | 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. |
| 12 | 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. |
| 13 | Is the patient still receiving treatment? | ☐ Yes<br>☐ No<br>☐ 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<br>☐ 3D conformal<br>☐ Brachytherapy HDR<br>☐ Brachytherapy LDR<br>☐ IMRT<br>☐ Proton Beam<br>☐ Stereotactic Body RT<br>☐ Stereotactic Radiosurgery<br>☐ WBRT<br>☐ Other (specify)<br>☐ 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<br>☐ No<br>☐ Unknown | 6379568 | Indicate whether the patient is still undergoing treatment. |