

Follow-Up Form Esophageal (ESCA)

Instructions: The Follow-up Form is to be completed 12 months after a case enters the Biospecimen Core Resource (BCR). All information provided on this form includes activity from the "Date of Last Contact" provided on the TCGA Enrollment Form to the most recent date of contact with the patient. This form should only be completed by the Tissue Source Site if updated information can be provided to TCGA. Please direct any questions to the Clinical Outreach team at the BCR.

Please note the following definitions for the "Unknown" and "Not Evaluated" answer options on this form.

Unknown: This answer option should only be selected if the TSS does not know this information after all efforts to obtain the data have been exhausted. If this answer option is selected for a question that is part of the TCGA required data set, the TSS must complete a discrepancy note providing a reason why the answer is unknown.

Not Evaluated: This answer option should only be selected by the TSS if it is known that the information being requested cannot be obtained. This could be because the test in question was never performed on the patient or the TSS knows that the information requested was never disclosed.

Tissue Source Site (TSS): _____ TSS Identifier: _____ TSS Unique Patient Identifier: _____

Completed By (Interviewer Name on OpenClinica): _____ Completed Date: _____

General Information

#	Data Element	Entry Alternatives	Working Instructions
1*	Has this TSS received permission from the NCI to provide time intervals as a substitute for requested dates on this form?	☐ Yes ☐ No	Please note that the time intervals must be recorded in place of dates where designated throughout this form if you have selected "yes" in the box. <i>Provided time intervals must begin with the date of initial pathologic diagnosis (i.e., biopsy or resection).</i> <i>Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.</i>
2*	Is this Patient Lost to Follow-up?	☐ Yes ☐ No	Indicate whether the patient is lost to follow-up, as defined by the ACoS Commission on Cancer. This only includes cases where updated follow-up information has not been collected within the past 15 months and all efforts to contact the patient have been exhausted (this includes reviewing the Social Security death index). If the patient is lost to follow-up, the remaining questions can be left unanswered. 61333 <i>If the patient is deceased and a TCGA follow-up form has not yet been completed, the answer to this question should be "no," and the remaining applicable questions should be completed.</i>

Follow-Up Information

#	Data Element	Entry Alternatives	Working Instructions
3*	Adjuvant (Post-Operative) Radiation Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative radiation therapy. <i>If the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed.</i> 2005312
4*	Adjuvant (Post-Operative) Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative pharmaceutical therapy. <i>If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.</i> 3397567
5	Tumor Status (at time of last contact or death)	☐ Tumor free ☐ With tumor ☐ Unknown	Indicate whether the patient was tumor/disease free at the date of last contact or death. 2759550
6*	Vital Status (at date of last contact)	☐ Living ☐ Deceased	Indicate whether the patient was living or deceased at the date of last contact. 5

Date of Last Contact (If patient is living)

Follow-Up Form Esophageal (ESCA)

#	Data Element	Entry Alternatives	Working Instructions
7	Date of Last Contact	_____ Month Day Year	If the patient is living, provide the date of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver). 2897020 (Month), 2897022 (Day), 2897024 (Year)
8	Number of Days from Date of Initial Pathologic Diagnosis to Date of Last Contact	_____	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of last contact. 3008273 <i>Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.</i>
Date of Death			
9	Date of Death	_____ Month Day Year	If the patient is deceased, provide the date of death. 2897026 (Month), 2897028 (Day), 2897030 (Year)
10	Number of Days from Date of Initial Pathologic Diagnosis to Date of Death	_____	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of death. 3165475 <i>Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.</i>
11*	Measure of success of outcome <u>at the completion of initial first course treatment</u>	☐ Progressive Disease ☐ Complete Response ☐ Stable Disease ☐ Unknown ☐ Partial Response ☐ Not Applicable (Treatment Ongoing)	Provide the patient's response to their initial first course treatment. 2786727
12*	Measure of Success of Outcome <u>at Completion of this Follow-up Form</u>	☐ Progressive Disease ☐ Partial Response ☐ Stable Disease ☐ Complete Response	Indicate the patient's measure of success at the time this follow-up form is completed. 3033278

New Tumor Event Information Complete this section if the patient had a new tumor event. If the patient did not have a new tumor event (or if the TSS does not know) indicate this in the question below, and the remainder of this section can be skipped.

Note: The New Tumor Event section on OpenClinica can be completed multiple times, if the patient had multiple New Tumor Events.

#	Data Element	Entry Alternatives	Working Instructions
13*	New Tumor Event After Initial Treatment?	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had a new tumor event (e.g. metastatic, recurrent, or new primary tumor) after the date of initial diagnosis. 3121376 <i>If the patient did not have a new tumor event or if this is unknown, the remaining questions can be skipped.</i>
14	Type of New Tumor Event	☐ Locoregional/Recurrence ☐ Distant Metastasis ☐ New Primary Tumor	Indicate whether the patient's new tumor event was a locoregional recurrence, a distant metastasis or a new primary tumor. 3119721
15	Site of New Tumor Event	☐ Lung ☐ Peritoneal Surfaces ☐ Non-Regional/Distant Lymph Nodes ☐ Liver ☐ Other, specify _____	Indicate the site of this new tumor event. 3108271
16	Other Site of New Tumor Event	_____	If the site of the new tumor event is not included in the provided list, describe the site of this new tumor event. 3128033

Date of New Tumor Event after Initial Treatment

17	Date of New Tumor Event	_____ Month Day Year	If the patient had a new tumor event, provide the date of diagnosis for this new tumor event. 3104044 (Month), 3104042 (Day), 3104046 (Year)
18	Number of Days from Date of Initial Pathologic Diagnosis to Date of New Tumor Event After Initial	_____	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of new tumor event after initial treatment. 3392464 <i>Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested</i>

Follow-Up Form Esophageal (ESCA)

#	Data Element	Entry Alternatives	Working Instructions
	Treatment		<i>dates on this form.</i>
19	Diagnostic Evidence of New Tumor Event	☐ Biopsy w/ Histologic Confirmation ☐ Convincing Imaging ☐ Positive Biomarker(s)	Indicate the procedure or testing method used to diagnose this new tumor event. 2786205
20	Additional Surgery for New Tumor Event	☐ Yes ☐ No ☐ Unknown	Using the patient's medical records, indicate whether the patient had surgery for the new tumor event in question. 3427611
<i>Date of Additional Surgery for New Tumor Event (when applicable)</i>			
21	Date of Additional Surgery for New Tumor Event	____ ____ ____ ____ ____ ____ <i>Month Day Year</i>	If the patient had surgery for the new tumor event, provide the date this surgery was performed. 3427612 (Month), 3427613 (Day), 3427614 (Year)
22	Number of Days from Date of Initial Pathologic Diagnosis to Date of Additional Surgery for New Tumor Event	_____	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of additional surgery for new tumor event (loco-regional). 3008335 <i>Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.</i>
23	Additional treatment for New Tumor Event: <i>Radiation Therapy</i>	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received radiation treatment for this new tumor event. 3427615
24	Additional treatment for New Tumor Event: <i>Pharmaceutical Therapy</i>	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received pharmaceutical treatment for this new tumor event. 3427616

 Principal Investigator or Designee Signature

 Print Name

 ____/____/_____
 Date