# Enrollment Form
Esophageal



**Instructions:** *The Enrollment Form should be completed for each TCGA qualified case, upon qualification notice from the BCR. All information provided on this form should include activity and known history from the date of initial diagnosis to the most recent date of contact with the patient ("Date of Initial Pathologic Diagnosis" and "Date of Last Contant" on this form).*

*Questions regarding this form should be directed to the Tissue Source Site's primary Clinical Outreach Contact 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 in 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<br>☐ No | If the answer to this question is yes, time intervals must be provided instead of dates, as indicated throughout this form.<br>*Provided time intervals must begin with the date of initial pathologic diagnosis (e.g. biopsy).*<br>*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.* |
| 2 | Is this a prospective tissue collection? | ☐ Yes<br>☐ No | Indicate whether the TSS providing tissue is contracted for prospective tissue collection. If the submitted tissue was collected for the specific purpose of TCGA, the tissue has been collected prospectively.<br>3088492 |
| 3 | Is this a retrospective tissue collection? | ☐ Yes<br>☐ No | Indicate whether the TSS providing tissue is contracted for retrospective tissue collection. If the submitted tissue was collected prior to the date the TCGA contract was executed, the tissue has been collected retrospectively.<br>3088528 |

## Patient Information

| # | Data Element | Entry Alternatives | | | Working Instructions |
|---|---|---|---|---|---|
| **Date of Birth** | | | | | |
| 4* | Date of Birth | ___ ___<br>Month | ___ ___<br>Day | ___ ___ ___ ___<br>Year | Provide the date the patient was born.<br>2896950(month), 2896952(day), 2896954 (year) |
| 5 | Number of Days from Date of Initial Pathologic Diagnosis to Date of Birth | _____ | | | Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the patient's date of birth.<br>3008233<br>*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.* |
| 6 | Country of Birth | _____ | | | Provide the country where the patient was born.<br>2183279 |

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Esophageal



| # | Data Element | Entry Alternatives | Working Instructions |
|---|---|---|---|
| 7* | Gender | ☐ Female<br>☐ Male | Provide the patient's gender using the defined categories.<br>2200604 |
| 8 | Height<br>*(at time of diagnosis)* | _____(cm) | Provide the patient's height (centimeters) at the time the patient was diagnosed with the tumor submitted for TCGA.<br>649 |
| 9 | Weight<br>*(at time of diagnosis)* | _____(kg) | Provide the patient's weight (kilograms) at the time the patient was diagnosed with the tumor submitted for TCGA.<br>651 |
| 10 | Country Where Cancer Sample was Procured | _____ | Provide the country where the tissue submitted for TCGA was procured.<br>3203072 |
| 11 | State/Province of Sample Procurement | _____ | Provide the name of the state, province or country where the sample submitted for TCGA was procured.<br>2179603 |
| 12 | City of Cancer Sample Procurement | _____ | Provide the name of the city where the sample submitted for TCGA was procured<br>3203075 |
| 13* | Race | ☐ American Indian or Alaska Native<br>*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.*<br>☐ Asian<br>*A person having origins in any of the original peoples of the far East, Southeast Asia, or in the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.*<br>☐ White<br>*A person having origins in any of the original peoples of the far Europe, the Middle East, or North Africa.*<br>☐ Black or African American<br>*A person having origins in any of any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."*<br>☐ Native Hawaiian or other Pacific Islander:<br>*A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.*<br>☐ Not Evaluated:<br>*Not provided or available.*<br>☐ Unknown:<br>*Could not be determined or unsure.* | Provide the patient's race using the defined categories.<br>2192199 |
| 14 | Ethnicity | ☐ Not Hispanic or Latino:<br>*A person not meeting the definition of Hispanic or Latino.*<br>☐ Hispanic or Latino:<br>*A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race.*<br>☐ Not Evaluated:<br>*Not provided or available.*<br>☐ Unknown:<br>*Could not be determined or unsure.* | Provide the patient's ethnicity using the defined categories.<br>2192217 |

# Enrollment Form
Esophageal



| # | Data Element | Entry Alternatives | Working Instructions |
|---|---|---|---|
| 15* | History of Prior Malignancy | ☐ Yes<br>☐ No | Indicate whether the patient was, at any time in their life, diagnosed with a malignancy prior to the diagnosis of the specimen submitted for TCGA. If the patient has had a prior malignancy, an additional form (the "Other Malignancy Form") must be completed for each prior malignancy. If the OMF was completed and submitted with the Initial Case Quality Control Form, the OMF does not need to be submitted a second time.<br>3382736<br>*If this question cannot be answered because the answer is unknown, the case will be excluded from TCGA.*<br>*If the patient has a history of multiple diagnoses of basal or squamous cell skin cancer, complete an OMF for the first diagnosis for each of these types.* |
| 16* | Neo-adjuvant Therapy (Pre-Operative) Therapy For Tumor Submitted for TCGA | ☐ Yes<br>☐ No | Indicate whether the patient received neo-adjuvant treatment (radiation, pharmaceutical, or both) prior to the collection of the tumor that yielded the sample submitted for TCGA.<br>3382737<br>*Systemic therapy and certain localized therapies (those administered to the same site as the TCGA submitted tissue) given prior to the collection of the sample submitted for TCGA is exclusionary.* |
| 17* | Tumor Status<br>*(at time of last contact or death)* | ☐ Tumor free<br>☐ With tumor<br>☐ Unknown | Indicate whether the patient was tumor/disease free at the date of last contact or death.<br>2759550 |
| 18* | Vital Status<br>*(at date of last contact)* | ☐ Living<br>☐ Deceased | Indicate whether the patient was living or deceased at the date of last contact.<br>2939553 |
| **Date of Last Contact** *(If patient is living)* | | | |
| 19* | Date of Last Contact | ___ ___ Month / ___ ___ Day / ___ ___ ___ ___ Year | If the patient is living, provide the month of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver).<br>2897020 (month), 2897022 (day), 2897024(year)<br>*Do not answer if patient is deceased.* |
| 20 | 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.<br>3008273<br>*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.* |
| **Date of Death** | | | |
| 21* | Date of Death | ___ ___ Month / ___ ___ Day / ___ ___ ___ ___ Year | If the patient is deceased, provide the month of death.<br>2897026(month), 2897028(day), 2897030 (year) |
| 22 | 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.<br>3165475<br>*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.* |
| **Patient History of Tobacco and Alcohol Use** | | | |
| 23 | Tobacco Smoking History Indicator | ☐ 1-Lifelong non-smoker (<100 cigarettes smoked in lifetime)<br>☐ 2-Current smoker (includes daily and non-daily smokers)<br>☐ 3-Current reformed smoker for > 15 years<br>☐ 4-Current reformed smoker for <= 15 years<br>☐ 5-Current reformed smoker (duration not specified)<br>☐ Smoking History not Documented | Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories. If the patient is a lifelong non-smoker, skip the additional smoking questions.<br>2181650 |

# Enrollment Form
Esophageal



| # | Data Element | Entry Alternatives | Working Instructions |
|---|---|---|---|
| 24 | Age at Onset of Tobacco Smoking | _____ | Provide the age in years when the patient began smoking cigarettes.<br>2178045<br>*If the patient is a lifelong non-smoker, do not answer this question.* |
| 25 | Year of Quitting Tobacco Smoking | ___ ___ ___ ___ (YYYY) | Provide the year the patient quit smoking.<br>2228610<br>*If the patient is a current smoker or a lifelong non-smoker, do not answer this question.* |
| 26 | Number of Pack Years Smoked | ___ ___ Pack Years | Provide the number of pack years the patient smoked. This is calculated using the number of cigarettes smoked per day times the number of years smoked, divided by 20. For example, if a patient smoked 5 cigarettes per day times 10 years divided by 20, the patient would have 2.5 pack years (e.g. 5 x 10/ 20=2.5).<br>2955385<br>*If the patient is a lifelong non-smoker, do not answer this question.* |
| 27 | Was the patient's alcohol history documented? | ☐ Yes<br>☐ No | Indicate whether the patient's alcohol history is documented.<br>3440205 |
| 28 | Frequency of Alcohol Consumption | ___ Days per Week | Provide the number of days per week that the patient consumes alcohol.<br>3114013<br>*If the patient's alcohol history is not documented, do not answer this question.* |
| 29 | Amount of Alcohol Consumption per Day | ___ ___ Drinks per Day | Provide the number of drinks the patient consumes per day.<br>3124961<br>*If the patient's alcohol history is not documented, do not answer this question.* |
| **Patient History of Esophageal and Gastric Disease** | | | |
| 30 | Did the patient have a prior clinical diagnosis of reflux disease? | ☐ Yes<br>☐ No<br>☐ Unknown | Indicate whether the patient had a prior clinical diagnosis of reflux disease.<br>3203079 |
| 31 | If the patient was clinically diagnosed with reflux disease, how was the patient treated?<br>*Check all that apply* | ☐ Medically Treated<br>☐ Surgically Treated<br>☐ No Treatment<br>☐ Unknown | If the patient was clinically diagnosed with reflux disease, indicated how the patient was treated.<br>3440206<br>*If the patient did not have a prior clinical diagnosis of reflux disease or if this is unknown, do not answer this question.* |
| 32 | Previous or current diagnosis of H. pylori infection? | ☐ Current<br>☐ Previous<br>☐ Never<br>☐ Unknown | Indicate whether the subject was previously or is currently diagnosed with H. Pylori.<br>3440211 |
| 33 | How was the patient initially diagnosed with esophageal cancer? | ☐ Screening<br>☐ Surveillance<br>☐ Symptomatic<br>☐ Unknown | Provide the method used to initially diagnose this patient with esophageal cancer.<br>3440213 |
| 34 | Prior to the diagnosis of the esophageal tumor submitted for TCGA, was the patient clinically diagnosed with Barrett's esophagus? | ☐ Yes-USA<br>☐ Yes-UK<br>☐ No<br>☐ Unknown | Indicate whether the subject was previously or is currently diagnosed with Barrett's Esophagus.<br>3440212 |
| 35 | If the patient had a clinical diagnosis of Barrett's esophagus, were goblet cells present? | ☐ Yes<br>☐ No<br>☐ Unknown | If the patient was clinically diagnosed with Barrett's Esophagus, indicate whether there were goblet cells present.<br>3440216<br>*If the patient did not have a clinical diagnosis of Barrett's Esophagus or if this is unknown, do not answer this question.* |

# Enrollment Form
Esophageal



| # | Data Element | Entry Alternatives | Working Instructions |
|---|---|---|---|
| 36 | Family History of Esophageal and/or Gastric Cancer in First Degree Relative *(parents, siblings, or children)* | ☐ Yes<br>☐ No<br>☐ Unknown | Indicate whether the subject has a first degree relative (parents, siblings, or children) with a history of esophageal cancer.<br>3440217 |
| 37 | Number of First Degree Relatives who have been Diagnosed with Esophageal and/or Gastric Cancer | _____ | Indicate the number of first degree relatives (parents, siblings, children) who have been diagnosed with esophageal cancer.<br>3440229<br>*If it is not known whether the patient had a family history of esophageal and/or gastric cancer, do not answer this question.* |

**Primary Tumor Pathologic/ Prognostic Information**

| # | Data Element | Entry Alternatives | Working Instructions |
|---|---|---|---|
| 38* | Primary Site of Disease | ☐ Esophagus | Using the patient's pathology/laboratory report, select the anatomic site of disease of the tumor submitted for TCGA.<br>2735776 |
| 39* | In which third of the esophagus is the tumor **centered**?<br>*Check only one.* | ☐ Proximal<br>☐ Mid<br>☐ Distal | Using the patient's pathology/laboratory report, indicate where the tumor submitted for TCGA is centered.<br>3295805 |
| 40* | In which third(s) of the esophagus is the tumor **involved**?<br>*Check all that apply.* | ☐ Proximal<br>☐ Mid<br>☐ Distal | Using the patient's pathology/laboratory report, indicate the involved locations of the tumor submitted for TCGA.<br>3295806 |
| 41* | Histological Type | ☐ Esophagus Adenocarcinoma, NOS<br>☐ Esophagus Squamous Cell Carcinoma | Using the patient's pathology/laboratory report, select the histology and/or subtype.<br>3081934 |
| 42 | Esophageal Columnar Metaplasia Present | ☐ Yes<br>☐ No<br>☐ Unknown | Indicate whether the patient had esophageal columnar metaplasia present.<br>3440218 |
| 43 | Goblet Cells of Esophageal Columnar Mucosa Present (i.e. Possible Specialized Barrett's Esophagus Mucosa) | ☐ Yes<br>☐ No<br>☐ Unknown | Indicate whether the patient had intestinal metaplasia with goblet cells present.<br>3440219 |
| 44 | Degree of Dysplasia within the Non-cancerous Esophageal Columnar Mucosa | ☐ Negative/ no dysplasia<br>☐ Indefinite for dysplasia<br>☐ Low grade dysplasia<br>☐ High grade dysplasia<br>☐ Unknown | Provide the patient's degree of dysplasia.<br>3440917 |
| 45* | Tumor Grade | ☐ GX – Unknown<br>☐ G1 – Well Differentiated<br>☐ G2 – Moderately Differentiated<br>☐ G3 – Poorly Differentiated | Using the patient's pathology/laboratory report, select the tumor grade for the specimen submitted for TCGA.<br>2785839 |

**Date and Method of Initial Pathologic Diagnosis**

| | | | | | |
|---|---|---|---|---|---|
| 46* | Date of Initial Pathologic Diagnosis | ___ ___<br>Month | ___ ___<br>Day | ___ ___ ___ ___<br>Year | Provide the month the patient was initially diagnosed with the malignancy submitted for TCGA.<br>2896956(month), 2896958(day), 2896960(year) |
| 47 | Age at Initial Diagnosis | _____ | | | Provide the age of the patient in years, at the time the patient was initially pathologically diagnosed.<br>2006657<br>*Only complete this question if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.* |

# Enrollment Form
Esophageal



| # | Data Element | Entry Alternatives | Working Instructions |
|---|---|---|---|
| 48 | Method of Initial Pathologic Diagnosis | ☐ Endoscopic Biopsy<br>☐ Transurethral Resection (TURBT)<br>☐ Other, specify | Provide the procedure used to initially diagnose the patient.<br>2757941 |
| 49 | Other Method of Initial Pathologic Diagnosis | _____ | If the procedure used to initially diagnose the patient was not included in the list provided, please describe the method used.<br>2757948 |
| **Lymph Node Status** | | | |
| 50 | Was there radiographic evidence suggesting spread to the lymph nodes? | ☐ Yes<br>☐ No<br>☐ Unknown | Indicate whether there was radiographic evidence of lymph nodes for this patient.<br>3440228 |
| 51 | Were lymph nodes examined at the time of primary resection? | ☐ Yes<br>☐ No<br>☐ Unknown | Indicate whether any lymph nodes were examined at the time of the primary resection.<br>2200396 |
| 52 | Number of Lymph Nodes Examined | _____ | Provide the number of lymph nodes examined, if one or more lymph nodes were removed.<br>3<br>*If lymph nodes were not examined for this patient at the time of the primary resection, or if this is unknown, do not answer this question.* |
| 53 | Number of Lymph Nodes Positive by H&E light microscopy | _____ | Provide the number of lymph nodes positive through hematoxylin and eosin (H&E) staining and light microscopy.<br>3086388<br>*If lymph nodes were not examined for this patient at the time of the primary resection, or if this is unknown, do not answer this question.* |
| 54 | Number of Lymph Nodes Positive by IHC Keratin Staining only | _____ | Provide the number of lymph nodes positive through keratin immunohistochemistry (IHC) staining.<br>3086383<br>*If lymph nodes were not examined for this patient at the time of the primary resection, or if this is unknown, do not answer this question.* |
| **AJCC Staging** *If the patient did not undergo surgery, the following questions should be completed.* | | | |
| 55* | AJCC Cancer Staging Edition<br>*(used for clinical staging)* | ☐ 1st Edition *(1978-1983)*<br>☐ 2nd Edition *(1984-1988)*<br>☐ 3rd Edition *(1989-1992)*<br>☐ 4th Edition *(1993-1997)*<br>☐ 5th Edition *(1998-2002)*<br>☐ 6th Edition *(2003-2009)*<br>☐ 7th Edition *(2010-present)* | Please provide the AJCC Cancer Staging Edition used to answer the following clinical staging questions.<br>2722309 |
| 56* | Clinical T Stage<br>*At time of biopsy* | ☐ TX ☐ T1 ☐ T4<br>☐ T0 ☐ T2 ☐ T4a<br>☐ Tis ☐ T3 ☐ T4b | Using the patient's medical records, select the code for the clinical T (primary tumor) defined by the American Joint Committee on Cancer (AJCC).<br>3440328 |
| 57* | Clinical N Stage<br>*At time of biopsy* | ☐ NX ☐ N1 ☐ N3<br>☐ N0 ☐ N2 | Using the patient's medical records, select the code for the clinical N (nodal) defined by the American Joint Committee on Cancer (AJCC).<br>3440330 |
| 58* | Clinical M Stage<br>*At time of biopsy* | ☐ MX ☐ M1 ☐ M1b<br>☐ M0 ☐ M1a | Using the patient's medical records, select the code for the clinical M (metastasis) defined by the American Joint Committee on Cancer (AJCC).<br>3440331 |
| 59* | Clinical Stage<br>*At time of biopsy* | ☐ Stage 0 ☐ Stage III<br>☐ Stage I ☐ Stage IIIA<br>☐ Stage IA ☐ Stage IIIB<br>☐ Stage IB ☐ Stage IIIC<br>☐ Stage II ☐ Stage IV<br>☐ Stage IIA ☐ Stage IVA<br>☐ Stage IIB ☐ Stage IVB | Using the patient's medical records, select the stage defined by the American Joint Committee on Cancer (AJCC).<br>3440332 |

# Enrollment Form
Esophageal



| # | Data Element | Entry Alternatives | Working Instructions |
|---|---|---|---|
| 60 | Will The Patient Undergo Surgery For This Tumor? | ☐ Yes<br>☐ No<br>☐ Surgery Already Performed<br>☐ Unknown | Indicate whether the patient has had surgery for this tumor.<br>3440231 |
| 61 | If Surgery Was Already Performed, Was Treatment Given Prior To Surgery? | ☐ No treatment<br>☐ Chemotherapy<br>☐ Radiation<br>☐ Chemotherapy & Radiation<br>☐ Unknown | If the patient has already undergone surgery, indicate whether the patient received treatment prior to the surgery.<br>3440232 |
| **AJCC Staging** *The following staging questions should be answered for* ***the pathologic staging done after the patient had surgery****.* *If the patient did not undergo surgery, additional questions should be answered for this patient (see questions 67-73).* | | | |
| 62* | AJCC Cancer Staging Edition | ☐ 1st Edition *(1978-1983)*<br>☐ 2nd Edition *(1984-1988)*<br>☐ 3rd Edition *(1989-1992)*<br>☐ 4th Edition *(1993-1997)*<br>☐ 5th Edition *(1998-2002)*<br>☐ 6th Edition *(2003-2009)*<br>☐ 7th Edition *(2010-present)* | Please use the AJCC Cancer Staging Edition used to answer the following pathologic staging questions.<br>2722309 |
| 63* | Pathologic Spread *(for Cystectomy Specimen):* Primary Tumor (pT) *Please provide as much information as possible.* | ☐ TX ☐ T1 ☐ T4<br>☐ T0 ☐ T2 ☐ T4a<br>☐ Tis ☐ T3 ☐ T4b<br>☐ Unknown | Using the patient's pathology/laboratory report, select the code for the pathologic T (primary tumor) defined by the American Joint Committee on Cancer (AJCC).<br>3045435 |
| 64* | Pathologic Spread *(for Cystectomy Specimen)*: Regional Nodes (pN) | ☐ NX ☐ N1 ☐ N3<br>☐ N0 ☐ N2 ☐ Unknown | Using the patient's pathology/laboratory report, select the code for the pathologic N (nodal) defined by the American Joint Committee on Cancer (AJCC).<br>3203106 |
| 65* | Distant Spread: Distant Metastasis (M) | ☐ MX ☐ M1 ☐ M1b<br>☐ M0 ☐ M1a ☐ Unknown | Using the patient's pathology/laboratory report, select the code for the pathologic M (metastasis) defined by the American Joint Committee on Cancer (AJCC).<br>3045439 |
| 66* | Tumor Stage | ☐ Stage 0 ☐ Stage IIA ☐ Stage IIIC<br>☐ Stage I ☐ Stage IIB ☐ Stage IV<br>☐ Stage IA ☐ Stage III ☐ Stage IVA<br>☐ Stage IB ☐ Stage IIIA ☐ Stage IVB<br>☐ Stage II ☐ Stage IIIB ☐ Unknown | Using the patient's pathology/laboratory report, select the stage defined by the American Joint Committee on Cancer (AJCC).<br>3203222 |
| 67* | Residual Tumor *(at time of initial surgery)* | ☐ RX ☐ R1 ☐ Unknown<br>☐ R0 ☐ R2 | Using the patient's pathology/laboratory report, select the tissue margin a status at time of surgical resection.<br>2608702 |
| 68 | Performance Status Scale: Karnofsky Score ***(To be taken prior to surgery / treatment.)*** | ☐ 100 – Normal, no complaints, no evidence of disease<br>☐ 90 – Able to carry on normal activity; minor signs or symptoms of disease<br>☐ 80 – Normal activity with effort; some signs or symptoms of disease<br>☐ 70 – Cares for self, unable to carry on normal activity or to do active work<br>☐ 60 – Requires occasional assistance, but is able to care for most of his/her needs<br>☐ 50 – Requires considerable assistance and frequent medical care<br>☐ 40 – Disabled, requires special care and assistance<br>☐ 30 – Severely disabled, hospitalization indicated. Death is not imminent.<br>☐ 20 – Very sick, hospitalization indicated. Death not imminent<br>☐ 10 – Moribund, fatal processes progressing rapidly<br>☐ 0 – Dead<br>☐ Unknown<br>☐ Not Evaluated | Provide the patient's Karnofsky Score using the defined categories. This score represents the functional capabilities of the patient at the time of the diagnosis of the tumor submitted for TCGA.<br>2003853 |

# Enrollment Form
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| # | Data Element | Entry Alternatives | Working Instructions |
|---|---|---|---|
| 69 | Performance Status Scale: Eastern Cooperative Oncology Group (ECOG) ***(To be taken prior to surgery / treatment.)*** | ☐ 0 – Asymptomatic<br>☐ 1 – Symptomatic but fully ambulatory<br>☐ 2 – Symptomatic but in bed less than 50% of the day<br>☐ 3 – Symptomatic and in bed more than 50% of the day<br>☐ 4 – Bedridden<br>☐ 5 – Dead<br>☐ Unknown<br>☐ Not Evaluated | Provide the patient's Eastern Cooperative Oncology Group (ECOG) score using the defined categories. This score represents the functional performance status of the patient at the time of the diagnosis of the tumor submitted for TCGA.<br>88 |
| 70* | Adjuvant (Post-Operative) Radiation Therapy | ☐ Yes<br>☐ No<br>☐ Unknown | Indicate whether the patient had adjuvant/ post-operative radiation therapy. ***IF the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed***.<br>2005312 |
| 71* | Adjuvant (Post-Operative) Pharmaceutical Therapy | ☐ Yes<br>☐ No<br>☐ Unknown | Indicate whether the patient had adjuvant/ post-operative pharmaceutical therapy. ***IF the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed***.<br>3397567 |

**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 |
|---|---|---|---|
| 72* | New Tumor Event After Initial Treatment? | ☐ Yes<br>☐ No<br>☐ Unknown | Indicate whether the patient had a new tumor event (e.g. metastatic, recurrent, or new primary tumor) after the date of initial diagnosis.<br>3121376<br>*If the patient did not have a new tumor event or if this is unknown, the remaining questions can be skipped.* |
| *Date of New Tumor Event after Initial Treatment* | | | |
| 73* | Month of New Tumor Event | ___ ___ ___ ___ ___ ___ ___ ___<br>Month Day Year | If the patient had a new tumor event, provide the date of diagnosis for this new tumor event.<br>3104044 (month), 3104042 (day), 3104046 (year) |
| 74 | Number of Days from Date of Initial Pathologic Diagnosis to Date of New Tumor Event After Initial Treatment | _____ | 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.<br>3392464<br>*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.* |
| 75 | Type of New Tumor Event | ☐ Locoregional/Recurrence<br>☐ Distant Metastasis<br>☐ New Primary Tumor | Indicate whether the patient's new tumor event was a locoregional recurrence, a distant metastasis or a new primary tumor.<br>3119721 |
| 76 | Site of New Tumor Event | ☐ Brain<br>☐ Lung<br>☐ Bone<br>☐ Liver<br>☐ Other, specify | Indicate the site of this new tumor event.<br>3108271 |
| 77 | 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.<br>3128033 |
| 78 | Diagnostic Evidence of New Tumor Event | ☐ Biopsy w/ Histologic Confirmation<br>☐ Convincing Imaging<br>☐ Positive Biomarker(s) | Indicate the procedure or testing method used to diagnose this new tumor event.<br>2786205 |

# Enrollment Form
Esophageal



| # | Data Element | Entry Alternatives | Working Instructions |
|---|---|---|---|
| 79 | Additional Surgery for New Tumor Event | ☐ Yes<br>☐ No<br>☐ Unknown | Using the patient's medical records, indicate whether the patient had surgery for the new tumor event in question.<br>3427611 |
| *Date of Additional Surgery for New Tumor Event (when applicable)* | | | |
| 80 | Date of Additional Surgery for New Tumor Event | ___ ___ ___ ___ ____ ____ ____ ____<br>Month Day Year | If the patient had surgery for the new tumor event, provide the date this surgery was performed.<br>3427612 (month), 3427613 (day), 3427614 (year) |
| 81 | 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).<br>3008335<br>*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.* |
| 82 | Additional treatment for New Tumor Event: *Radiation Therapy* | ☐ Yes<br>☐ No<br>☐ Unknown | Indicate whether the patient received radiation treatment for this new tumor event.<br>3427615 |
| 83 | Additional treatment for New Tumor Event: *Pharmaceutical Therapy* | ☐ Yes<br>☐ No<br>☐ Unknown | Indicate whether the patient received pharmaceutical treatment for this new tumor event.<br>3427616 |

_____

Principal Investigator Signature Date

***I acknowledge that the above information provided by my institution is true and correct and has been quality controlled.***