Enrollment Form Bladder (BLCA)

Completed Date: _____

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 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 Contact" 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): _____

| Gene | ieneral 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 | If the answer to this question is yes, time intervals must be provided instead of dates, as indicated throughout this form. Provided time intervals must begin with the date of initial pathologic diagnosis (e.g. biopsy). 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 □ 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. <u>3088492</u> | | |
| 3 | Is this a retrospective tissue collection? | □ Yes □ 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. <u>3088528</u> | | |

Patient Information

| # | Data Element | Entr | y Alternatives | | Working Instructions |
|-----|----------------|--|---|--|---|
| Dat | e of Birth | | | | |
| 4 | Month of Birth | □ 01 □ 04 □ 02 □ 05 □ 03 □ 06 | □ 07 □ 08 □ 09 | □ 10 □ 11 □ 12 | Provide the month the patient was born. <u>2896950</u> |
| 5 | Day of Birth | 01 08 02 09 03 10 04 11 05 12 06 13 07 | 14 20 15 21 16 22 17 23 18 24 19 25 | □ 26 □ 27 □ 28 □ 29 □ 30 □ 31 | Provide the day the patient was born. 2896952 |
| 6 | Year of Birth | | | _ | Provide the year the patient was born. <u>2896954</u> |

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| # | Data Element | Entry Alternatives | Working Instructions |
|----|--|---|--|
| 7 | 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. <u>3008233</u> 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. |
| 8 | Gender | ☐ Female ☐ Male | Provide the patient's gender using the defined categories. $\underline{2200604}$ |
| 9 | Height (at time of diagnosis) | (cm) | Provide the patient's height (in centimeters) at the time the patient was diagnosed with the malignancy being submitted for TCGA. <u>649</u> |
| 10 | Weight (at time of diagnosis) | (kg) | Provide the patient's weight (in kilograms) at the time the patient was diagnosed with the malignancy being submitted for TCGA. <u>651</u> |
| 11 | Race | 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. Asian 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. White A person having origins in any of the original peoples of the far Europe, the Middle East, or North Africa. Black or African American | Provide the patient's race using the defined categories. 2192199 |
| 12 | Ethnicity | Not Hispanic or Latino: A person not meeting the definition of Hispanic or Latino. Hispanic or Latino: A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. Not Evaluated Not provided or available. Unknown Could not be determined or unsure. | Provide the patient's ethnicity using the defined categories. 2192217 |
| 13 | History of Prior Malignancy | □ Yes □ 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. <u>3382736</u> If this question cannot be answered because the answer is unknown, the case will be excluded from TCGA. 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. |

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| # | Data Element | Entry Alternatives | Working Instructions |
|-----|--|---|---|
| 14 | History of Neo-adjuvant Treatment for Sample Submitted for TCGA | □ Yes □ No | Indicate whether the patient received neo-adjuvant treatment (radiation, pharmaceutical, or both) prior to the collection of the sample submitted for TCGA. 3382737Systemic therapy and certain localized therapies (those administered to the same site as the TCGA submitted sample) given prior to the collection of the sample submitted for TCGA is exclusionary.BCG treatment prior to procurement is acceptable, if administered at least 90 days prior to tumor procurement. |
| 15 | Does the patient have a history of non-muscle invasive bladder cancer? | ☐ Yes □ No □ Unknown | Indicate whether the patient has a history of non-muscle invasive bladder cancer. <u>3436253</u> |
| 16 | If the patient does have a history of non-muscle invasive bladder cancer, how was the patient treated? <i>Check all that apply</i> | | If the patient has a history of non-muscle invasive bladder cancer, indicate the type of treatment given for the non-muscle tumor.3436357Note: Intravesical chemotherapy is not allowable. |
| 17 | If this patient received BCG treatment, was it given within 90 days from the resection date of the muscle invasive bladder tumor submitted for TCGA? | □ Yes □ No | If the patient received BCG treatment for the tumor submitted for TCGA, indicate whether this treatment was given within 90 days of the resection of this tumor. <u>3436260</u> |
| 18 | If this patient received BCG treatment, did the patient have a complete response? | □ Yes □ No □ Unknown | If the patient received BCG treatment, indicate whether the patient had a complete response. A complete response includes normal cytology, normal cytology, and a negative biopsy (if performed). 3436262 |
| 19 | If this patient received BCG treatment, did the patient complete one or more induction courses? | ☐ Yes □ No □ Unknown | If the patient received BCG treatment, indicate whether the patient completed one or more induction courses. 3436265 |
| 20 | If this patient received BCG treatment, did the patient complete one or more maintenance courses? | ☐ Yes ☐ No ☐ Unknown | If the patient received BCG treatment, indicate whether the patient completed one or more maintenance courses. <u>3436266</u> |
| 21 | If this patient received BCG treatment and had a complete response, how long was this maintained from the first BCG instillation? | months | If the patient received BCG treatment, provide the number of months the complete response was maintained, beginning with the initial date that complete response was documented. 3436267 |
| 22 | 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. <u>2759550</u> |
| 23 | Vital Status (at date of last contact) | □ Living □ Deceased | Indicate whether the patient was living or deceased at the date of last contact. <u>2939553</u> |
| Dat | e of Last Contact (If patier | nt is living) | |
| 24 | Month of Last Contact | ¹ 01 ¹ 04 ¹ 07 ¹ 10 ⁰ 02 ⁰ 05 ⁰ 08 ¹ 11 ⁰ 03 ⁰ 06 ⁰ 09 ¹ 12 | 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). 2897020 Do not answer if patient is deceased. |

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| # | Data Element | | Entr | y Alterna | atives | | Working Instructions |
|-----|---|--|--|--|--|--|---|
| 25 | Day of Last Contact | 01 02 03 04 05 06 07 | 08 09 10 11 12 13 | 14 15 16 17 18 19 | 20 21 22 23 24 25 | □ 26 □ 27 □ 28 □ 29 □ 30 □ 31 | If the patient is living, provide the day of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver). <u>2897022</u> <i>Do not answer if patient is deceased.</i> |
| 26 | Year of Last Contact | | | | | | If the patient is living, provide the year of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver). <u>2897024</u> <i>Do not answer if patient is deceased.</i> |
| 27 | 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. <u>3008273</u> 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. |
| Dat | e of Death | | | | | | |
| 28 | Month of Death | □ 01 □ 02 □ 03 | □ 04 □ 05 □ 06 | | 07 08 09 | □ 10 □ 11 □ 12 | If the patient is deceased, provide the month of death. <u>2897026</u> |
| 29 | Day of Death | 01 02 03 04 05 06 07 | 08 09 10 11 12 13 | 14 15 16 17 18 19 | 20 21 22 23 24 25 | □ 26 □ 27 □ 28 □ 29 □ 30 □ 31 | If the patient is deceased, provide the day of death. 2897028 |
| 30 | Year of Death | | | | | | If the patient is deceased, provide the year of death. 2897030 |
| 31 | 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. <u>3165475</u> Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested |
| 32 | Current Occupation | | | | | | dates on this form.Provide the patient's current occupation or their occupation at death. Current occupations can include homemaker, student, or retired.2435398 |
| 33 | Primary Occupation | | | | | | Provide the occupation in which the patient was employed for the majority of their working years. Primary occupations can include homemaker and student. 5714 |
| 34 | Primary Occupation: Chemical Exposure | | | | | | Provide any chemical exposure the patient had during their working years in their primary occupation. <u>2596673</u> |
| 35 | Primary Occupation: In what type of industry was the patient employed? | | | | | | Provide the industry of the patient's primary occupation. <u>3135408</u> |
| 36 | Primary Occupation: How many years has the patient worked in this occupation? | | | | | | Provide the number of years the patient was employed in their primary occupation. 2435424 |

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| # | Data Element | Entry Alt | ernatives | Working Instructions |
|----|---|--|---|--|
| 37 | Tobacco smoking history indicator | 1-Lifelong non-smok smoked in lifetime) 2-Current smoker (in daily smokers) 3-Current reformed 4-Current reformed years 5-Current reformed specified) Smoking History not | ker (<100 cigarettes ncludes daily and non- smoker for > 15 years smoker for <= 15 smoker (duration not | 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. <u>2181650</u> |
| 38 | Age of onset tobacco smoking | Ye | ears of Age | Provide the age in years when the patient began smoking cigarettes. <u>2178045</u> If the patient is a lifelong non-smoker, do not answer this question. |
| 39 | Year of quitting tobacco smoking | (YYYY) | | Provide the year the patient quit smoking. <u>2228610</u> If the patient is a lifelong non-smoker or if the patient has not quit smoking, do not answer this question. |
| 40 | Number of Pack Years Smoked | 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). <u>2955385</u> If the patient is a lifelong non-smoker, do not answer this question. |
| 41 | Blood Relative Cancer History | Relative Mother Father Grandmother Grandfather Sister Brother Child | Cancer Type | Provide any first degree blood relatives with a known history of cancer. <u>2783641</u> Provide the cancer diagnosis of any known relatives with a history cancer. <u>2195089</u> |
| 42 | Adjuvant (Post- Operative) Radiation Therapy | □ Yes □ No □ Unknown | | Indicate whether the patient had adjuvant/ post- operative radiation therapy. <i>IF the patient did have</i> <i>adjuvant radiation, the Radiation Supplemental Form</i> <i>should be completed.</i> <u>2005312</u> |
| 43 | Adjuvant (Post- Operative) Pharmaceutical Therapy | □ Yes □ No □ Unknown | | Indicate whether the patient had adjuvant/ post- operative pharmaceutical therapy. <i>IF the patient did</i> <i>have adjuvant pharmaceutical therapy, the</i> <i>Pharmaceutical Supplemental Form should be completed.</i> <u>3397567</u> |
| 44 | Measure of success of outcome <u>at the</u> <u>completion of initial</u> <u>first course treatment</u> | Progressive Disease Stable Disease Partial Response Complete Response Unknown Not Applicable | | Provide the patient's response to their initial first course treatment. <u>2786727</u> |

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| # | Data Element | Entry Alternatives | Working Instructions |
|----|---|---|--|
| 45 | Performance Status Scale: Karnofsky Score (To be taken prior to surgery/treatment) | Interview interview 100 - Normal, no complaints, no evidence of disease 90 - Able to carry on normal activity; minor signs or symptoms of disease 80 - Normal activity with effort; some signs or symptoms of disease 70 - Cares for self, unable to carry on normal activity or to do active work 60 - Requires occasional assistance, but is able to care for most of his/her needs 50 - Requires considerable assistance and frequent medical care 40 - Disabled, requires special care and assistance 30 - Severely disabled, hospitalization indicated. Death is not imminent. 20 - Very sick, hospitalization indicated. Death not imminent 10 - Moribund, fatal processes progressing rapidly 0 - Dead ECOG has been provided; Karnofsky Score not required. Unknown Not Evaluated | Provide either the Karnofsky or the ECOG performance status score. If the ECOG performance score is provided, select the last answer option. 2003853 |
| 46 | Performance Status Scale: Eastern Cooperative Oncology Group (ECOG) (To be taken prior to surgery/treatment) | 0 - Asymptomatic 1 - Symptomatic but fully ambulatory 2 - Symptomatic but in bed less than 50% of the day 3 - Symptomatic and in bed more than 50% of the day 4 - Bedridden Karnofsky Score has been provided; ECOG not required. Unknown Not Evaluated | Provide either the Karnofsky or the ECOG performance status score. If the Karnofsky performance score is provided, select the last answer option. <u>88</u> |

Pathologic/Prognostic Information

| # | Data Element | Entry Alternatives | Working Instructions |
|----|-------------------------|--|---|
| 47 | Primary Site of Disease | □ Bladder | Using the patient's pathology/laboratory report, select the anatomic site of disease of the tumor submitted for TCGA. <u>2735776</u> |
| 48 | Histological Subtype | Muscle invasive urothelial carcinoma (pT2 or above) | Using the patient's pathology/laboratory report, select the histology and/or subtype of the tumor submitted for TCGA. <u>2831122</u> |
| 49 | Diagnosis subtype | PapillaryNon-papillary | Using the patient's pathology/laboratory report, indicate whether the disease was papillary or non-papillary. 2783887 |
| 50 | Tumor Grade | □ Low Grade □ High Grade □ Unknown | Using the patient's pathology/laboratory report, select the tumor grade. <u>2867375</u> If the following descriptions are used for grade, please assign the provided grade as noted below: • GX (Grade cannot be assessed) = Unknown • G1 (Well differentiated) = Low Grade • G2 (Moderately differentiated) = High Grade • G3 (Poorly differentiated) = High Grade • G4 (Undifferentiated) = High Grade |

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| # | Data Element | Entry Alterna | | Working Instructions |
|------|--|---|---|--|
| 51 | Anatomic Organ Sub- Division Check all that apply | DomeINeckITrigoneI | Wall, NOS Wall, anterior Wall, lateral Wall, posterior | Using the patient's pathology/laboratory report, select all areas of tumor invasion. <u>2008006</u> |
| Date | e and Method of Initial Pa | athologic Diagnosis | | |
| 52 | Month of Initial Pathologic Diagnosis | 01 04 0 02 05 0 03 06 0 | 08 11 09 12 | Provide the month the patient was initially pathologically diagnosed with the malignancy submitted for TCGA. <u>2896956</u> |
| 53 | Day of Initial Pathologic Diagnosis | $ \begin{array}{c ccccccccccccccccccccccccccccccccccc$ | $ \begin{array}{c ccccccccccccccccccccccccccccccccccc$ | Provide the day the patient was initially pathologically diagnosed with the malignancy submitted for TCGA. 2896958 |
| 54 | Year of Initial Pathologic Diagnosis | | | Provide the year the patient was initially pathologically diagnosed with the malignancy submitted for TCGA. 2896960 |
| | | | | Provide the age of the patient in years, at the time the patient was initially pathologically diagnosed. 2006657 |
| 55 | Age at Initial Diagnosis | | | 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. |
| | Method of Initial | □ Endoscopic biopsy | | Provide the procedure used to initially diagnose the patient. <u>2757941</u> |
| 56 | Pathologic Diagnosis | Transurethral resection (Other, specify | (TURBT) | Please note that this method is referring to the procedure performed on the Date of Initial Pathologic Diagnosis, provided in the previous question. |
| 57 | Other Method of Pathologic Diagnosis | | | If the procedure used to initially diagnose the patient was not included in the list provided, please describe the method used. 2757948 |
| AJC | C Staging | | | |
| 58 | AJCC Cancer Staging Edition | 1st Edition (1978-1983) 2nd Edition (1984-1988) 3rd Edition (1989-1992) 4th Edition (1993-1997) 5th Edition (1998-2002) 6th Edition (2003-2009) 7th Edition (2010-present) | | Please select the AJCC Cancer Staging Edition used to answer the following questions. <u>2722309</u> |
| 59 | Clinical Assessment (TURBT and EUA): Primary Tumor (T) Complete this question in the absence of a cystectomy specimen. Please provide as much information as possible. | Tis Tis T1 T1 | ГЗ, NOS ГЗа ГЗb Г4, NOS Г4а | Using the patient's pathology/laboratory report, select the code for the clinical T (primary tumor) defined by the American Joint Committee on Cancer (AJCC). 3135236 |
| 60 | Pathologic Stage (for Cystectomy Specimen): Primary Tumor (pT) Please provide as much information as possible. | pT0 pT pTis p pTa p pT1 p pT2 p | oT2b oT3 oT3a oT3b oT4 oT4a oT4b | 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). <u>3045435</u> |
| 61 | Lymphovascular Invasion | ☐ Yes □ No □ Unknown | | Indicate whether large vessel (vascular) invasion and/or small, thin-walled (lymphatic) invasion was detected. <u>64727</u> |

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| # | Data Element | Entry Alte | rnatives | Working Instructions |
|-----|---|--|---|---|
| | Pathologic Spread(for | | DpN2 | Using the patient's pathology/laboratory report, select the code for the pathologic N (nodal) defined by the American |
| 62 | <i>Cystectomy Specimen</i>): Regional Nodes (pN) | | □ pN3 □ pN4 | Joint Committee on Cancer (AJCC). 3203106 |
| Lyn | 1ph Node Status (Complet | - | • | <u>3203100</u> |
| Lyn | Were Lymph Nodes | □ Yes | ny was perjormeaj | Indicate whether any lymph nodes were examined at the time |
| 63 | Examined at the Time | □ No □ Unknown | | of the primary resection. <u>2200396</u> |
| | of Primary Resection? Number of Lymph | | | Provide the number of lymph nodes examined, if one or more |
| 64 | Nodes Examined | | | lymph nodes were removed. <u>3</u> |
| 65 | 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. <u>3086388</u> |
| 66 | Extracapsular Extension | □ Yes □ No □ Unknown | | Using the patient's pathology/laboratory report, indicate whether there was extracapsular extension. <u>64165</u> |
| 67 | If Extracapsular Extension present | □ Focal□ Extensive□ Unknown | | If there was extracapsular extension present, indicate whether the extension was focal or extensive. If extracapsular extension was not present, skip this question. <u>3130374</u> |
| 68 | Distant Spread: Distant Metastasis (M) | □ MX □ M0 □ M1 | | Using the patient's pathology/laboratory report, select the code for the pathologic M (metastasis) defined by the American Joint Committee on Cancer (AJCC). <u>3045439</u> <i>Please provide clinical evidence (often imaging) strong enough to determine patient treatment OR Histological confirmation when available.</i> |
| 69 | Metastatic Site (check all that apply) | Lymph node only Lung Liver Bone Other, specify None | | If the patient had a metastatic tumor at the time of initial diagnosis of the tumor submitted for TCGA, provide the site of the metastasis. If there was more than one metastatic site, select all that apply. 62835 |
| 70 | Other Metastatic Site | | | If the site of the metastasis was not included in the list provided, please provide the site. <u>3135371</u> |
| 71 | Tumor Stage | □ Stage 0is | Stage II Stage III Stage IV | Using the patient's pathology/laboratory report, select the stage defined by the American Joint Committee on Cancer (AJCC). <u>3203222</u> |
| 72 | Did the patient have incidental prostate cancer? | □ Yes □ No □ Unknown | | Using the patient's pathology/laboratory report, indicate whether incidental prostate cancer was found at the time of the bladder cancer diagnosis. If there was no incidental prostate cancer, skip any related questions. <u>3135387</u> |
| 73 | Pathologic Spread for Incidental Prostate Cancer | pT0 pT1, NOS pT1a pT1b pT1c | □ pT2a □ pT2b □ pT2c □ pT3, NOS □ pT3a □ pT3b □ pT4 | If incidental prostate cancer was discovered, select the code for the pathologic T (primary tumor) defined by the American Joint Committee on Cancer (AJCC). <u>3135398</u> |
| 74 | Gleason Score (If patient had incidental prostate cancer) | □ 3 □ 4 □ 5 | □ 7 □ 8 □ 9 □ 10 □ Unknown | If incidental prostate cancer was discovered, select the Gleason score (a prognostic measure obtained by adding the primary and secondary patterns) for the prostate cancer. <u>2634976</u> |

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| New ' | ew 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. | | | | | |
|-----------|--|---|---|--|--|--|
| # | Data Element | Entry Alternatives | Working Instructions | | | |
| 75 | 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. <u>3121376</u> If the patient did not have a new tumor event or if this is unknown, the remaining questions can be skipped. | | | |
| Date | e of New Tumor Event after | Initial Treatment | | | | |
| <u>76</u> | Month of New Tumor Event | 01 04 07 10 02 05 08 11 03 06 09 12 | If the patient had a new tumor event, provide the month of diagnosis for this new tumor event. <u>3104044</u> | | | |
| <u>77</u> | Day of New Tumor Event | $ \begin{array}{c ccccccccccccccccccccccccccccccccccc$ | If the patient had a new tumor event, provide the day of diagnosis for this new tumor event. <u>3104042</u> | | | |
| <u>78</u> | Year of New Tumor Event | | If the patient had a new tumor event, provide the year of diagnosis for this new tumor event. <u>3104046</u> | | | |
| <u>79</u> | 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. <u>3392464</u> 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. | | | |
| <u>80</u> | Type of New Tumor Event | Locoregional (Urothelial tumor event) 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. <u>3119721</u> | | | |
| <u>81</u> | Site of New Tumor Event | Renal Pelvis Ureter Bladder Urethra Other, specify Lymph Node Only | If the patient had a new tumor event, provide the site of this tumor. 3108271 | | | |
| <u>82</u> | 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. <u>3128033</u> | | | |
| <u>83</u> | 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 | | | |
| Date | | New Tumor Event (when applicable) | | | | |
| <u>84</u> | Month of Additional Surgery for New Tumor Event | 01 04 07 10 02 05 08 11 03 06 09 12 | If the patient had surgery for the new tumor event, provide the month this surgery was performed. <u>3427612</u> | | | |
| <u>85</u> | Day of Additional Surgery for New Tumor Event | $ \begin{array}{c ccccccccccccccccccccccccccccccccccc$ | If the patient had surgery for the new tumor event, provide the day this surgery was performed. 3427613 | | | |
| <u>86</u> | Year of Additional Surgery for New Tumor | | If the patient had surgery for the new tumor event, provide the year this surgery was performed. 3427614 | | | |

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| # | Data Element | Entry Alternatives | Working Instructions |
|-----------|---|----------------------------|--|
| | Event | | |
| <u>87</u> | 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). <u>3008335</u> 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. |
| <u>88</u> | 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. <u>3427615</u> |
| <u>89</u> | Additional treatment for New Tumor Event: Pharmaceutical Therapy | ☐ Yes ☐ No ☐ Unknown | Indicate whether the patient received pharmaceutical treatment for this new tumor event. <u>3427616</u> |

Principal Investigator or Designee Signature

Print Name

/ ____ / ____ / ____ ___ Date