

Follow-Up Form Bladder (BLCA)

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?	<input type="checkbox"/> Yes <input type="checkbox"/> 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). 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?	<input type="checkbox"/> Yes <input type="checkbox"/> 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	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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. 2005312
4	Adjuvant (Post-Operative) Pharmaceutical Therapy	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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. 3397567
5	Tumor Status (at time of last contact or death)	<input type="checkbox"/> Tumor free <input type="checkbox"/> With tumor <input type="checkbox"/> 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)	<input type="checkbox"/> Living <input type="checkbox"/> Deceased	Indicate whether the patient was living or deceased at the date of last contact. 2939553

Follow-Up Form Bladder (BLCA)

#	Data Element	Entry Alternatives	Working Instructions
Date of Last Contact (<i>If patient is living</i>)			
7	Month of Last Contact	<input type="checkbox"/> 01 <input type="checkbox"/> 04 <input type="checkbox"/> 07 <input type="checkbox"/> 10 <input type="checkbox"/> 02 <input type="checkbox"/> 05 <input type="checkbox"/> 08 <input type="checkbox"/> 11 <input type="checkbox"/> 03 <input type="checkbox"/> 06 <input type="checkbox"/> 09 <input type="checkbox"/> 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
8	Day of Last Contact	<input type="checkbox"/> 01 <input type="checkbox"/> 08 <input type="checkbox"/> 14 <input type="checkbox"/> 20 <input type="checkbox"/> 26 <input type="checkbox"/> 02 <input type="checkbox"/> 09 <input type="checkbox"/> 15 <input type="checkbox"/> 21 <input type="checkbox"/> 27 <input type="checkbox"/> 03 <input type="checkbox"/> 10 <input type="checkbox"/> 16 <input type="checkbox"/> 22 <input type="checkbox"/> 28 <input type="checkbox"/> 04 <input type="checkbox"/> 11 <input type="checkbox"/> 17 <input type="checkbox"/> 23 <input type="checkbox"/> 29 <input type="checkbox"/> 05 <input type="checkbox"/> 12 <input type="checkbox"/> 18 <input type="checkbox"/> 24 <input type="checkbox"/> 30 <input type="checkbox"/> 06 <input type="checkbox"/> 13 <input type="checkbox"/> 19 <input type="checkbox"/> 25 <input type="checkbox"/> 31 <input type="checkbox"/> 07	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). 2897022
9	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). 2897024
10	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			
11	Month of Death	<input type="checkbox"/> 01 <input type="checkbox"/> 04 <input type="checkbox"/> 07 <input type="checkbox"/> 10 <input type="checkbox"/> 02 <input type="checkbox"/> 05 <input type="checkbox"/> 08 <input type="checkbox"/> 11 <input type="checkbox"/> 03 <input type="checkbox"/> 06 <input type="checkbox"/> 09 <input type="checkbox"/> 12	If the patient is deceased, provide the month of death. 2897026
12	Day of Death	<input type="checkbox"/> 01 <input type="checkbox"/> 08 <input type="checkbox"/> 14 <input type="checkbox"/> 20 <input type="checkbox"/> 26 <input type="checkbox"/> 02 <input type="checkbox"/> 09 <input type="checkbox"/> 15 <input type="checkbox"/> 21 <input type="checkbox"/> 27 <input type="checkbox"/> 03 <input type="checkbox"/> 10 <input type="checkbox"/> 16 <input type="checkbox"/> 22 <input type="checkbox"/> 28 <input type="checkbox"/> 04 <input type="checkbox"/> 11 <input type="checkbox"/> 17 <input type="checkbox"/> 23 <input type="checkbox"/> 29 <input type="checkbox"/> 05 <input type="checkbox"/> 12 <input type="checkbox"/> 18 <input type="checkbox"/> 24 <input type="checkbox"/> 30 <input type="checkbox"/> 06 <input type="checkbox"/> 13 <input type="checkbox"/> 19 <input type="checkbox"/> 25 <input type="checkbox"/> 31 <input type="checkbox"/> 07	If the patient is deceased, provide the day of death. 2897028
13	Year of Death	_____	If the patient is deceased, provide the year of death. 2897030
14	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>
15	Measure of success of outcome <i>at the completion of initial first course treatment</i>	<input type="checkbox"/> Progressive Disease <input type="checkbox"/> Partial Response <input type="checkbox"/> Stable Disease <input type="checkbox"/> Unknown <input type="checkbox"/> Complete Response <input type="checkbox"/> Not Applicable	Provide the patient's response to their initial first course treatment. 2786727
16	Measure of Success of Outcome <i>at Completion of this Follow-up Form</i>	<input type="checkbox"/> Progressive Disease <input type="checkbox"/> Stable Disease <input type="checkbox"/> Complete Response <input type="checkbox"/> Partial 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
23	New Tumor Event After Initial Treatment?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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>

Follow-Up Form

Bladder (BLCA)

#	Data Element	Entry Alternatives	Working Instructions
<i>Date of New Tumor Event after Initial Treatment</i>			
<u>24</u>	Month of New Tumor Event	<input type="checkbox"/> 01 <input type="checkbox"/> 04 <input type="checkbox"/> 07 <input type="checkbox"/> 10 <input type="checkbox"/> 02 <input type="checkbox"/> 05 <input type="checkbox"/> 08 <input type="checkbox"/> 11 <input type="checkbox"/> 03 <input type="checkbox"/> 06 <input type="checkbox"/> 09 <input type="checkbox"/> 12	If the patient had a new tumor event, provide the month of diagnosis for this new tumor event. 3104044
<u>25</u>	Day of New Tumor Event	<input type="checkbox"/> 01 <input type="checkbox"/> 08 <input type="checkbox"/> 14 <input type="checkbox"/> 20 <input type="checkbox"/> 26 <input type="checkbox"/> 02 <input type="checkbox"/> 09 <input type="checkbox"/> 15 <input type="checkbox"/> 21 <input type="checkbox"/> 27 <input type="checkbox"/> 03 <input type="checkbox"/> 10 <input type="checkbox"/> 16 <input type="checkbox"/> 22 <input type="checkbox"/> 28 <input type="checkbox"/> 04 <input type="checkbox"/> 11 <input type="checkbox"/> 17 <input type="checkbox"/> 23 <input type="checkbox"/> 29 <input type="checkbox"/> 05 <input type="checkbox"/> 12 <input type="checkbox"/> 18 <input type="checkbox"/> 24 <input type="checkbox"/> 30 <input type="checkbox"/> 06 <input type="checkbox"/> 13 <input type="checkbox"/> 19 <input type="checkbox"/> 25 <input type="checkbox"/> 31 <input type="checkbox"/> 07	If the patient had a new tumor event, provide the day of diagnosis for this new tumor event. 3104042
<u>26</u>	Year of New Tumor Event	_____	If the patient had a new tumor event, provide the year of diagnosis for this new tumor event. 3104046
<u>27</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. 3392464 <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>
<u>28</u>	Type of New Tumor Event	<input type="checkbox"/> Locoregional (<i>Urothelial tumor event</i>) <input type="checkbox"/> Distant Metastasis <input type="checkbox"/> New Primary Tumor	Indicate whether the patient's new tumor event was a locoregional recurrence, a distant metastasis or a new primary tumor. 3119721
<u>29</u>	Site of New Tumor Event	<input type="checkbox"/> Renal Pelvis <input type="checkbox"/> Lymph Node Only <input type="checkbox"/> Ureter <input type="checkbox"/> Lung <input type="checkbox"/> Bladder <input type="checkbox"/> Bone <input type="checkbox"/> Urethra <input type="checkbox"/> Liver <input type="checkbox"/> Other, specify	Indicate the site of this new tumor event. 3108271
<u>30</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. 3128033
<u>31</u>	Additional Surgery for New Tumor Event	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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>			
<u>32</u>	Month of Additional Surgery for New Tumor Event	<input type="checkbox"/> 01 <input type="checkbox"/> 04 <input type="checkbox"/> 07 <input type="checkbox"/> 10 <input type="checkbox"/> 02 <input type="checkbox"/> 05 <input type="checkbox"/> 08 <input type="checkbox"/> 11 <input type="checkbox"/> 03 <input type="checkbox"/> 06 <input type="checkbox"/> 09 <input type="checkbox"/> 12	If the patient had surgery for the new tumor event, provide the month this surgery was performed. 3427612
<u>33</u>	Day of Additional Surgery for New Tumor Event	<input type="checkbox"/> 01 <input type="checkbox"/> 08 <input type="checkbox"/> 14 <input type="checkbox"/> 20 <input type="checkbox"/> 26 <input type="checkbox"/> 02 <input type="checkbox"/> 09 <input type="checkbox"/> 15 <input type="checkbox"/> 21 <input type="checkbox"/> 27 <input type="checkbox"/> 03 <input type="checkbox"/> 10 <input type="checkbox"/> 16 <input type="checkbox"/> 22 <input type="checkbox"/> 28 <input type="checkbox"/> 04 <input type="checkbox"/> 11 <input type="checkbox"/> 17 <input type="checkbox"/> 23 <input type="checkbox"/> 29 <input type="checkbox"/> 05 <input type="checkbox"/> 12 <input type="checkbox"/> 18 <input type="checkbox"/> 24 <input type="checkbox"/> 30 <input type="checkbox"/> 06 <input type="checkbox"/> 13 <input type="checkbox"/> 19 <input type="checkbox"/> 25 <input type="checkbox"/> 31 <input type="checkbox"/> 07	If the patient had surgery for the new tumor event, provide the day this surgery was performed. 3427613
<u>34</u>	Year of Additional Surgery for New Tumor Event	_____	If the patient had surgery for the new tumor event, provide the year this surgery was performed. 3427614
<u>35</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). 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>

Follow-Up Form
Bladder (BLCA)

#	Data Element	Entry Alternatives	Working Instructions
<u>36</u>	Additional treatment for New Tumor Event: <i>Radiation Therapy</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient received radiation treatment for this new tumor event. 3427615
<u>37</u>	Additional treatment for New Tumor Event: <i>Pharmaceutical Therapy</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient received pharmaceutical treatment for this new tumor event. 3427616

Principal Investigator or Designee Signature_____
Print Name____/____/_____
Date