

Follow-Up Form

Cholangiocarcinoma (CHOL)

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*	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
2*	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 <u>for the tumor submitted for TCGA</u> . 2005312 <i>If the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed.</i>
3*	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 <u>for the tumor submitted for TCGA</u> . 3397567 <i>If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.</i>
4*	Adjuvant (Post-Operative) Ablation or Embolization Therapy	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient had adjuvant/ post-operative ablation or embolization therapy <u>for the tumor submitted for TCGA</u> . 3172120 <i>If the patient did have ablation/embolization treatment for this new tumor event, the Ablation/Embolization Supplemental Form should be completed.</i>
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

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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. 5
Date of Last Contact (If patient is living)			
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) Do not answer if patient is deceased.
Date of Death			
10	Date of Death	____/____/____ (month)* (day) (year)*	If the patient is deceased, provide the date of death. 2897026 (month), 2897028 (day), 2897030 (year)

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?	<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 initial treatment. 3121376 If the patient did not have a new tumor event or if this is unknown, the remaining questions can be skipped.
14	Type of New Tumor Event	<input type="checkbox"/> Locoregional (Contiguous with tumor bed) <input type="checkbox"/> Intrahepatic Recurrence (New tumor distant from surgery site) <input type="checkbox"/> Extrahepatic Recurrence (Please specify anatomic site) <input type="checkbox"/> New Primary Tumor (Please specify anatomic site)	Indicate whether the patient's new tumor event was a locoregional recurrence, a distant metastasis or a new primary tumor. A new primary tumor is a tumor with a different histology than the tumor submitted to TCGA. 3119721
15	Anatomic Site of New Tumor Event	<input type="checkbox"/> Peritoneum <input type="checkbox"/> Perihilar lymph node <input type="checkbox"/> Distant lymph node <input type="checkbox"/> Lung <input type="checkbox"/> Bone <input type="checkbox"/> Liver <input type="checkbox"/> Brain <input type="checkbox"/> Other (Please 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
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)
20	Was Liver Transplant Performed in Conjunction with New Tumor Event	<input type="checkbox"/> Yes <input type="checkbox"/> No	If the patient had a new tumor event, indicate whether a liver transplant was performed in conjunction with the new tumor event. 3168060
21	Date of Liver Transplant	____/____/____ (month)* (day) (year)*	If the patient had a liver transplant in conjunction with the new tumor event, provide the date of the liver transplant. 3168022 (month), 3168021 (day), 3168037 (year)
24	Additional treatment for New Tumor Event: Surgery	<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
25	Date of Additional Surgery for New Tumor Event	____/____/____ (month)* (day) (year)*	If the patient had surgery for the new tumor event, provide the date this surgery was performed. 3427612 (month), 3427613 (day), 3427614 (year)

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#	Data Element	Entry Alternatives	Working Instructions
<u>28</u>	Residual Tumor <i>After surgery for New Tumor Event</i>	<input type="checkbox"/> RX: The presence of residual tumor or margin status cannot be assessed. <input type="checkbox"/> R0: No residual tumor and negative microscopic margins in resected specimen. <input type="checkbox"/> R1: Microscopic residual tumor. No gross residual disease but positive microscopic margins. <input type="checkbox"/> R2: Macroscopic residual tumor. Grossly visible residual disease.	Using the patient's pathology/laboratory report, select the residual tumor status after the surgical resection for the new tumor event. 3104061
<u>29</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>30</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 <i>Note: Pharmaceutical treatment includes chemotherapy, immunotherapy, hormonal therapy, and targeted molecular therapy.</i>
<u>31</u>	Additional treatment of New Tumor Event <i>Ablation/ Embolization Therapy</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient received or is currently receiving ablation/embolization treatment for this new tumor event. 3173961
Time Intervals: The following questions are only to be answered if the Tissue Source Site is unable to provide the dates requested on this form. <i>Please Note: 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>			
i	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. Please Note: Provided time intervals must begin with the date of initial pathologic diagnosis. (i.e., biopsy or resection)
ii	Number of Days from Date of Definitive Surgical Procedure to Date of Last Contact	_____	Provide the number of days from the date of definitive surgical procedure for the disease described on this form to the date of last contact. 4461931
iii	Number of Days from Date of Definitive Surgical Procedure to Date of Death	_____	Provide the number of days from the date of definitive surgical procedure for the disease described on this form to the date of death. 4461932
iv	Number of Days from Date of Definitive Surgical Procedure to Date of New Tumor Event After Initial Treatment	_____	Provide the number of days from the date of definitive surgical procedure for the disease described on this form to the date of new tumor event after initial treatment. 4461933
v	Number of Days from Date of Definitive Surgical Procedure to Date of Liver Transplant	_____	Provide the number of days from the date of definitive surgical procedure for the disease described on this form to the date of the liver transplant. 4461934
vi	Number of Days from Date of Definitive Surgical Procedure to Date of Additional Surgery for New Tumor Event	_____	Provide the number of days from the date of definitive surgical procedure for the disease described on this form to the date of additional surgery for new tumor event. 4461935

Principal Investigator or Designee Signature

Print Name

Date (Month/Day/Year)