

Follow-Up Form

Acute Myeloid Leukemia (LAML)

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). 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	Radiation Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had radiation therapy <i>for the sample submitted for TCGA. IF the patient did have radiation, the Radiation Supplemental Form should be completed.</i> 2005312
4	Transplantation	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had a bone marrow transplant. 3131750
5	Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had pharmaceutical therapy <i>for the sample submitted for TCGA. IF the patient did have pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.</i> 3397567

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#	Data Element	Entry Alternatives	Working Instructions
6	Vital Status (at date of last contact)	☐ Living ☐ Deceased	Indicate whether the patient was living or deceased at the date of last contact. 2939553
Date of Last Contact (If patient is living)			
7	Month of Last Contact	☐ 01 ☐ 04 ☐ 07 ☐ 10 ☐ 02 ☐ 05 ☐ 08 ☐ 11 ☐ 03 ☐ 06 ☐ 09 ☐ 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	☐ 01 ☐ 08 ☐ 14 ☐ 20 ☐ 26 ☐ 02 ☐ 09 ☐ 15 ☐ 21 ☐ 27 ☐ 03 ☐ 10 ☐ 16 ☐ 22 ☐ 28 ☐ 04 ☐ 11 ☐ 17 ☐ 23 ☐ 29 ☐ 05 ☐ 12 ☐ 18 ☐ 24 ☐ 30 ☐ 06 ☐ 13 ☐ 19 ☐ 25 ☐ 31 ☐ 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	☐ 01 ☐ 04 ☐ 07 ☐ 10 ☐ 02 ☐ 05 ☐ 08 ☐ 11 ☐ 03 ☐ 06 ☐ 09 ☐ 12	If the patient is deceased, provide the month of death. 2897026
12	Day of Death	☐ 01 ☐ 08 ☐ 14 ☐ 20 ☐ 26 ☐ 02 ☐ 09 ☐ 15 ☐ 21 ☐ 27 ☐ 03 ☐ 10 ☐ 16 ☐ 22 ☐ 28 ☐ 04 ☐ 11 ☐ 17 ☐ 23 ☐ 29 ☐ 05 ☐ 12 ☐ 18 ☐ 24 ☐ 30 ☐ 06 ☐ 13 ☐ 19 ☐ 25 ☐ 31 ☐ 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>	☐ Persistent Disease ☐ Complete Remission ☐ Patient Deceased ☐ Unknown ☐ 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>	☐ Persistent Disease ☐ Complete Remission ☐ Patient Deceased ☐ Unknown	Indicate the patient's measure of success at the time this follow-up form is completed. 3033278
17	Time to Neutrophil Recovery	_____ days (days to ANC >1000 per mcl)	Provide the number of days required for the patient's neutrophil count to recover to at least 1000 per cubic millimeter. 3138062
18	Time to Platelet Recovery	_____ days (days to platelet count >100,000 per mcl)	Provide the number of days required for the patient's platelet count to recover to at least 100,000 per cubic milliliter. 3138066

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#	Data Element	Entry Alternatives	Working Instructions
19	Performance Status Scale: Karnofsky Score (To be taken prior to surgery/treatment)	☐ 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	Using the patient's medical records, provide the Karnofsky performance status score at the time provided in the "Timing" question below. 2003853
20	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	Using the patient's medical records, provide the ECOG performance status score at the time provided in the "Timing" question below. 88
21	Performance Status Scale: Timing	☐ Induction ☐ Salvage ☐ Re-induction ☐ Maintenance ☐ Consolidation ☐ Other, specify	Indicate the patient's status during the last documented ECOG and/or Karnofsky performance status score. 2792763
22	Other Performance Status Scale: Timing	_____	If the status of the patient during the last documented ECOG and/or Karnofsky performance score was not included in the provided list, specify the patient's status. 3151756

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?	☐ 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>
Date of New Tumor Event after Initial Treatment			
24	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. 3104044
25	Day of New Tumor Event	☐ 01 ☐ 08 ☐ 14 ☐ 20 ☐ 26 ☐ 02 ☐ 09 ☐ 15 ☐ 21 ☐ 27 ☐ 03 ☐ 10 ☐ 16 ☐ 22 ☐ 28 ☐ 04 ☐ 11 ☐ 17 ☐ 23 ☐ 29 ☐ 05 ☐ 12 ☐ 18 ☐ 24 ☐ 30 ☐ 06 ☐ 13 ☐ 19 ☐ 25 ☐ 31 ☐ 07	If the patient had a new tumor event, provide the day of diagnosis for this new tumor event. 3104042
26	Year of New Tumor Event	_____	If the patient had a new tumor event, provide the year of diagnosis for this new tumor event. 3104046

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#	Data Element	Entry Alternatives	Working Instructions
27	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>
28	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
29	Site of New Tumor Event	☐ Bone Marrow ☐ Brain ☐ Lung ☐ Bone ☐ Liver ☐ Other, specify _____	Indicate the site of this new tumor event. 3108271
30	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
31	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. 3008755
<i>Date of Additional Surgery for New Tumor Event (when applicable)</i>			
32	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. 2897038
33	Day of Additional Surgery for New Tumor Event	☐ 01 ☐ 08 ☐ 14 ☐ 20 ☐ 26 ☐ 02 ☐ 09 ☐ 15 ☐ 21 ☐ 27 ☐ 03 ☐ 10 ☐ 16 ☐ 22 ☐ 28 ☐ 04 ☐ 11 ☐ 17 ☐ 23 ☐ 29 ☐ 05 ☐ 12 ☐ 18 ☐ 24 ☐ 30 ☐ 06 ☐ 13 ☐ 19 ☐ 25 ☐ 31 ☐ 07	If the patient had surgery for the new tumor event, provide the day this surgery was performed. 2897040
34	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. 2897042
35	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>
36	Additional treatment for New Tumor Event: Radiation Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received radiation treatment for this new tumor event. 3008761
37	Additional treatment for New Tumor Event: Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received pharmaceutical treatment for this new tumor event. 2650646

Principal Investigator or Designee Signature

Print Name

Date