

Enrollment Form

Acute Myeloid Leukemia (LAML)

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): _____ 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	If the answer to this question is yes, time intervals must be provided instead of dates, as indicated throughout this form. <i>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.</i>
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. 3088492
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. 3088528

Patient Information

#	Data Element	Entry Alternatives	Working Instructions
Date of Birth			
4	Month of Birth	☐ 01 ☐ 04 ☐ 07 ☐ 10 ☐ 02 ☐ 05 ☐ 08 ☐ 11 ☐ 03 ☐ 06 ☐ 09 ☐ 12	Provide the month the patient was born. 2896950
5	Day of Birth	☐ 01 ☐ 08 ☐ 14 ☐ 20 ☐ 02 ☐ 09 ☐ 15 ☐ 21 ☐ 26 ☐ 03 ☐ 10 ☐ 16 ☐ 22 ☐ 27 ☐ 04 ☐ 11 ☐ 17 ☐ 23 ☐ 28 ☐ 05 ☐ 12 ☐ 18 ☐ 24 ☐ 29 ☐ 06 ☐ 13 ☐ 19 ☐ 25 ☐ 30 ☐ 07 ☐ 31	Provide the day the patient was born. 2896952
6	Year of Birth	_____	Provide the year the patient was born. 2896954

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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. 3008233 <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>
8	Gender	☐ Female ☐ Male	Provide the patient's gender using the defined categories. 2200604
9	Race	☐ American Indian or Alaska Native <i>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.</i> ☐ Asian <i>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.</i> ☐ White <i>A person having origins in any of the original peoples of the far Europe, the Middle East, or North Africa.</i> ☐ Black or African American <i>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."</i> ☐ Native Hawaiian or other Pacific Islander: <i>A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.</i> ☐ Not Evaluated: <i>Not provided or available.</i> ☐ Unknown: <i>Could not be determined or unsure.</i>	Provide the patient's race using the defined categories. 2192199
10	Ethnicity	☐ Not Hispanic or Latino: <i>A person not meeting the definition of Hispanic or Latino.</i> ☐ Hispanic or Latino: <i>A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race.</i> ☐ Not Evaluated: <i>Not provided or available.</i> ☐ Unknown: <i>Could not be determined or unsure.</i>	Provide the patient's ethnicity using the defined categories. 2192217
11	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. 3382736 <i>If this question cannot be answered because the answer is unknown, the case will be excluded from TCGA.</i> <i>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.</i>
12	History of Prior Hematologic Disorder	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient has a history of hematologic disorders. 3120971
13	History of Neo-adjuvant Treatment for Sample Submitted for TCGA (excluding hydroxyurea)	☐ Yes ☐ No	Indicate whether the patient received neo-adjuvant treatment (radiation, pharmaceutical, or both) prior to the collection of the sample submitted for TCGA. 3382737 <i>Systemic 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.</i>

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14	Did patient receive hydroxyurea prior to procurement?	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received hydroxyurea prior to procurement of the specimen submitted for TCGA. 3121638
15	Days of Hydroxyurea Treatment	_____	If the patient received hydroxyurea treatment prior to the procurement of the specimen submitted for TCGA, provide the number of days hydroxyurea was given. 2724416
16	Cumulative Dose of Hydroxyurea Treatment	_____ mg	If the patient received hydroxyurea treatment prior to the procurement of the specimen submitted for TCGA, provide the cumulative dose of hydroxyurea administered. 1515
18	Did patient receive ATRA (aka Vesinoid or Tretinoin) treatment prior to procurement?	☐ Yes ☐ No	Indicate whether the patient received ATRA (aka Vesinoid or Tretinoin) prior to the procurement of the specimen submitted for TCGA. If the patient did receive this treatment prior to procurement, this case will be excluded from TCGA. 3121640 <i>If the answer to this question is yes, this case will be excluded.</i>
19	Did patient receive steroids for this malignancy prior to procurement?	☐ Yes ☐ No	Indicate whether the patient received steroids prior to the procurement of the specimen submitted for TCGA. If the patient did receive this treatment prior to procurement, this case will be excluded from TCGA. 3121323 <i>If the answer to this question is yes, this case will be excluded.</i>
20	Previous Exposure to Non-Medical Potentially Leukemogenic Agents	☐ None ☐ Benzene ☐ Radiation ☐ Pesticides ☐ Unknown ☐ Other, specify _____	Indicate whether the patient has a history of exposure to non-medical potentially leukemogenic agents. 3121309
21	Other Chemical Exposure	_____	If the patient was exposed to non-medical potentially leukemogenic agents and the type of exposure was not included in the provide list, specify the type of exposure. 3131188
22	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)			
23	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 <i>Do not answer if patient is deceased.</i>
24	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 <i>Do not answer if patient is deceased.</i>
25	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 <i>Do not answer if patient is deceased.</i>
26	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>

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#	Data Element	Entry Alternatives	Working Instructions
Date of Death			
27	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
28	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
29	Year of Death	_____	If the patient is deceased, provide the year of death. 2897030
30	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>
31	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
32	Transplantation	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had a bone marrow transplant. 3131750
33	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
34	Measure of success of outcome <i>at the completion of initial first course treatment</i>	☐ Persistent Disease ☐ Unknown ☐ Complete Remission ☐ Not Applicable ☐ Patient Deceased	Provide the patient's response to their initial first course treatment. 2786727
35	Performance Status Scale: Karnofsky Score	☐ 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 ☐ Unknown ☐ Not Evaluated	Provide the patient's Karnofsky Score using the defined categories. This score represents the functional capabilities of the patient. 2003853

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#	Data Element	Entry Alternatives	Working Instructions
36	Performance Status Scale: Eastern Cooperative Oncology Group (ECOG) <i>(To be taken prior to surgery/treatment)</i>	☐ 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 ☐ Unknown ☐ 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. 88
37	Performance Status Scale: Timing	☐ Induction ☐ Re-induction ☐ Consolidation ☐ Salvage ☐ Maintenance ☐ Other ☐ Unknown ☐ Not Applicable	Provide a time reference for the Karnofsky score and/or the ECOG score using the defined categories. 2792763 <i>If ECOG or Karnofsky Scores were not evaluated, select Not Applicable.</i>
38	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

Pathologic/Prognostic Information

#	Data Element	Entry Alternatives	Working Instructions
39	Primary Site of Disease	☐ Bone Marrow	Using the patient's pathology/laboratory report, select the anatomic site of disease of the tumor submitted for TCGA. 2735776
40	Source of Cells used for Analysis	☐ Bone Marrow Aspirate ☐ Peripheral Blood	Using the laboratory report, provide the source of cells used for analysis. 64583
Date and Method of Initial Pathologic Diagnosis			
41	Month of Initial Pathologic Diagnosis	☐ 01 ☐ 04 ☐ 07 ☐ 10 ☐ 02 ☐ 05 ☐ 08 ☐ 11 ☐ 03 ☐ 06 ☐ 09 ☐ 12	Provide the month the patient was initially pathologically diagnosed with the malignancy submitted for TCGA. 2896956
42	Day of Initial Pathologic Diagnosis	☐ 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	Provide the day the patient was initially pathologically diagnosed with the malignancy submitted for TCGA. 2896958
43	Year of Initial Pathologic Diagnosis	_____	Provide the year the patient was initially pathologically diagnosed with the malignancy submitted for TCGA. 2896960
44	Age at Initial Melanoma Diagnosis	_____	Provide the age of the patient in years, at the time the patient was initially pathologically diagnosed with melanoma. 2006657 <i>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.</i>
45	Method of Initial Pathologic Diagnosis	☐ Core Biopsy ☐ Bone Marrow Aspirate ☐ Blood Draw	Provide the procedure used to initially diagnose the patient. 2757941 <i>Please note that this method is referring to the procedure performed on the Date of Initial Pathologic Diagnosis, provided in the previous question.</i>
46	Percent Blasts Peripheral Blood at diagnosis	_____ %	Using the pathology/laboratory report, provide the percent blasts in the peripheral blood. 58282

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47	FAB Category for Bone Marrow <i>(If available)</i>	☐ Classified by WHO only ☐ M3v ☐ Biophenotypic ☐ M4 ☐ M0 Undifferentiated ☐ M4eos ☐ M1 ☐ M5 ☐ M2 ☐ M6 ☐ M3 ☐ M7	Using the pathology/laboratory report, provide the patient's French American British (FAB) morphologic classification of leukemia. If the FAB classification is not available for this patient, provide the WHO classification below. 3124352																																																																																																																																							
48	AML World Health Organization (WHO) <i>(If available)</i>	☐ Classified by FAB Only ☐ AML with t(8;21)(q22;q22), RUNX1 RUNX1T1 ☐ AML with inv(16)(p13q22) or t(16;16)(p13.1;q22), (CBFβ/MYH11) ☐ AML with t(9;11)(p22;q33);MLLT3-MLL ☐ AML with t(6;9)(p23;q34);DEK-NUP214 ☐ AML with inv(3)(q21;q26.2) or t(3;3)(q21;q26.2);RPNI-EVI1 ☐ AML (megakaryoblastic) with t(1;22)(p13;q13); RBM15-MKL1 ☐ AML with mutated NPM1 ☐ AML with mutated CEBPA ☐ AML with minimal differentiation ☐ AML without maturation ☐ AML with maturation ☐ Acute myelomonocytic leukemia ☐ Acute monoblastic/monocytic leukemia ☐ Acute erythroid leukemia ☐ Erythroleukemia, erythroid/myeloid ☐ Acute megakaryoblastic leukemia ☐ Acute basophilic leukemia ☐ Acute panmyelosis with myelofibrosis ☐ AML with myelodysplasia-related changes	Using the pathology/laboratory report, provide the patient's World Health Organization classification, when available. If the WHO classification is not available for this patient, provide the FAB classification above. 3257714																																																																																																																																							
49	Immunophenotype & Cytochemistry	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2">Test</th><th colspan="3">Outcome</th></tr> <tr> <th>Negative</th><th>Positive, %</th><th>Not Tested</th></tr> </thead> <tbody> <tr><td>NA</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____ %</td><td style="text-align: center;">☐</td></tr> <tr><td>MPX</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____ %</td><td style="text-align: center;">☐</td></tr> <tr><td>NSE</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____ %</td><td style="text-align: center;">☐</td></tr> <tr><td>TDT</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____ %</td><td style="text-align: center;">☐</td></tr> <tr><td>CD3</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____ %</td><td style="text-align: center;">☐</td></tr> <tr><td>CD4</td><td 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<tr><td>CD79a</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____ %</td><td style="text-align: center;">☐</td></tr> <tr><td>CD117</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____ %</td><td style="text-align: center;">☐</td></tr> <tr><td>HLA-DR</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____ %</td><td style="text-align: center;">☐</td></tr> <tr><td>PAX5</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____ %</td><td style="text-align: center;">☐</td></tr> <tr><td>MPO</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____ %</td><td style="text-align: center;">☐</td></tr> <tr><td>Other CD:</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____ %</td><td style="text-align: center;">☐</td></tr> </tbody> </table>	Test	Outcome			Negative	Positive, %	Not Tested	NA	☐	_____ %	☐	MPX	☐	_____ %	☐	NSE	☐	_____ %	☐	TDT	☐	_____ %	☐	CD3	☐	_____ %	☐	CD4	☐	_____ %	☐	CD5	☐	_____ %	☐	CD7	☐	_____ %	☐	CD10	☐	_____ %	☐	CD11c	☐	_____ %	☐	CD11d	☐	_____ %	☐	CD13	☐	_____ %	☐	CD14	☐	_____ %	☐	CD15	☐	_____ %	☐	CD19	☐	_____ %	☐	CD20	☐	_____ %	☐	CD23	☐	_____ %	☐	CD25	☐	_____ %	☐	CD33	☐	_____ %	☐	CD34	☐	_____ %	☐	CD36	☐	_____ %	☐	CD38	☐	_____ %	☐	CD45	☐	_____ %	☐	CD56	☐	_____ %	☐	CD64	☐	_____ %	☐	CD65	☐	_____ %	☐	CD79a	☐	_____ %	☐	CD117	☐	_____ %	☐	HLA-DR	☐	_____ %	☐	PAX5	☐	_____ %	☐	MPO	☐	_____ %	☐	Other CD:	☐	_____ %	☐	Using the pathology/laboratory report, provide the patient's immunophenotype & cytochemistry results. If the test was positive, provide the percent positive when available. 3121483 and 3121491
Test	Outcome																																																																																																																																									
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CD64	☐	_____ %	☐																																																																																																																																							
CD65	☐	_____ %	☐																																																																																																																																							
CD79a	☐	_____ %	☐																																																																																																																																							
CD117	☐	_____ %	☐																																																																																																																																							
HLA-DR	☐	_____ %	☐																																																																																																																																							
PAX5	☐	_____ %	☐																																																																																																																																							
MPO	☐	_____ %	☐																																																																																																																																							
Other CD:	☐	_____ %	☐																																																																																																																																							

Enrollment Form

Acute Myeloid Leukemia (LAML)

#	Data Element	Entry Alternatives	Working Instructions
50	Percent (%) Cellularity	_____ %	Using the patient's pathology/laboratory report, provide the percent cellularity. 58264
Complete Blood Count (Within 24 Hours of Banking)			
51	WBC (x10e3 per mcl)	_____	Using the patient's pathology/laboratory report, provide the patient's white blood cell count (x10e3 per mcl). 2006107
52	Hemoglobin (g/dL)	_____	Using the patient's pathology/laboratory report, provide the patient's hemoglobin (g/dL). 2190
53	Hematocrit (%)	_____ %	Using the patient's pathology/laboratory report, provide the patient's hematocrit (%). 2180444
54	Platelets (x10e6 mcl)	_____	Using the patient's pathology/laboratory report, provide the patient's platelet count (x10e6 mcl). 58304
Differential Count, Bone Marrow (Within 24 Hours of Banking)			
55	Blasts	_____ %	Using the patient's pathology/laboratory report, provide the patient's blast percentage. 58262
56	Promyelocytes	_____ %	Using the patient's pathology/laboratory report, provide the patient's promyelocyte percentage. 58271
57	Myelocytes	_____ %	Using the patient's pathology/laboratory report, provide the patient's myelocyte percentage. 2669788
58	Metamyelocytes	_____ %	Using the patient's pathology/laboratory report, provide the patient's metamyelocyte percentage. 2669787
59	Bands	_____ %	Using the patient's pathology/laboratory report, provide the patient's bands percentage. 3131180
60	Segs (Neutrophils)	_____ %	Using the patient's pathology/laboratory report, provide the patient's neutrophil percentage. 2669786
61	Eosinophils	_____ %	Using the patient's pathology/laboratory report, provide the patient's eosinophil percentage. 58266
62	Basophils	_____ %	Using the patient's pathology/laboratory report, provide the patient's basophil percentage. 64507
63	Lymphocytes	_____ %	Using the patient's pathology/laboratory report, provide the patient's lymphocyte percentage. 58270
64	Monocytes	_____ %	Using the patient's pathology/laboratory report, provide the patient's monocyte percentage. 58301
65	Prolymphocytes	_____ %	Using the patient's pathology/laboratory report, provide the patient's prolymphocyte percentage. 2669789
66	Promonocytes	_____ %	Using the patient's pathology/laboratory report, provide the patient's promonocyte percentage. 3131695
67	Abnormal	_____ %	Using the patient's pathology/laboratory report, provide the patient's percentage of abnormal cells. 3144381
	Total	100%	
68	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
69	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

Enrollment Form

Acute Myeloid Leukemia (LAML)

#	Data Element	Entry Alternatives	Working Instructions																								
70	Were Routine Cytogenetics Done?	☐ Yes ☐ No ☐ Unknown	Indicate whether routine cytogenetic were performed for this patient. 2626417																								
71	Total Number of Metaphases	_____	Using the patient's pathology/laboratory report, provide the total number of metaphases for this patient. 64523																								
72	Cytogenetic Risk Group (CALGB Criteria)	☐ Favorable ☐ Intermediate/Normal ☐ Poor ☐ N/A – Remission	Using the Cancer and Leukemia Group B (CALGB) criteria, indicate the patient's cytogenetic risk group. 3121502																								
73	Cytogenetic Analysis Abnormality Type (Check all that apply)	☐ Normal ☐ Not Tested ☐ Complex ☐ inv(3) ☐ t(3;3) ☐ -5, del(5q) or t(5q) ☐ -7, del(7q) or t(7q) ☐ +8 ☐ +9 ☐ Trisomy 4 ☐ del(17p) ☐ t(4;11) ☐ t(9;22) ☐ t(21;21) ☐ inv(16) ☐ t(6;9) ☐ t(8;21) ☐ t(9;11) ☐ t(15;17) ☐ del(20q) ☐ -13 del(13q) ☐ (q22;q22) ☐ 3q ☐ 5q- ☐ 7q- ☐ Other, specify	Using the patient's laboratory report, provide any cytogenetic abnormalities found. 2760451																								
74	Other Cytogenetic Analysis Abnormality Type	_____	If the cytogenetic abnormalities were found for this patient and they are not including in the provided list, specify the abnormalities found. 2957553																								
75	Was FISH Performed?	☐ Yes ☐ No ☐ Unknown	Indicate whether Fluorescence In Situ Hybridization (FISH) testing was performed for this patient. 64521 <i>If FISH was not performed, the related questions can be skipped.</i>																								
76	Was FISH Abnormality Detected?	☐ Yes ☐ No ☐ Unknown	If FISH testing was performed for this patient, indicate whether abnormalities were found. 3121563																								
77	For FISH Tested Indicate % (0-100)	<table border="1"> <tbody> <tr><td>BCR-ABL</td><td>_____ %</td></tr> <tr><td>PML-RAR</td><td>_____ %</td></tr> <tr><td>MLL</td><td>_____ %</td></tr> <tr><td>CBFB</td><td>_____ %</td></tr> <tr><td>AML1-ETO</td><td>_____ %</td></tr> <tr><td>TEL-AML 1</td><td>_____ %</td></tr> <tr><td>+8</td><td>_____ %</td></tr> <tr><td>-7 or del(7q)</td><td>_____ %</td></tr> <tr><td>-5 or del(5q)</td><td>_____ %</td></tr> <tr><td>del (20q)</td><td>_____ %</td></tr> <tr><td>Other</td><td>_____ %</td></tr> <tr><td>Total</td><td>100%</td></tr> </tbody> </table>	BCR-ABL	_____ %	PML-RAR	_____ %	MLL	_____ %	CBFB	_____ %	AML1-ETO	_____ %	TEL-AML 1	_____ %	+8	_____ %	-7 or del(7q)	_____ %	-5 or del(5q)	_____ %	del (20q)	_____ %	Other	_____ %	Total	100%	If FISH testing was performed for this patient and FISH abnormalities were found, provide the percentages for each abnormality. 2322156 , 3151691
BCR-ABL	_____ %																										
PML-RAR	_____ %																										
MLL	_____ %																										
CBFB	_____ %																										
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-5 or del(5q)	_____ %																										
del (20q)	_____ %																										
Other	_____ %																										
Total	100%																										
78	Were other molecular studies performed?	☐ Yes ☐ No ☐ Unknown	Indicate whether molecular studies were performed for this patient. 3121565 <i>If other molecular studies were not performed, the related questions can be skipped.</i>																								
79	Type of Molecular Analysis	☐ Southern ☐ RT-PCR ☐ Other, specify ☐ Unknown	If molecular studies were performed for this patient, indicate the type of analysis that was done. 3121575																								
80	Other Type of Analysis	_____	If molecular studies were performed for this patient, and the type of analysis is not included in the provided list, specify the type of analysis done. 3151694																								

Enrollment Form

Acute Myeloid Leukemia (LAML)

#	Data Element	Entry Alternatives	Working Instructions																																																																																				
81	Were Molecular Abnormalities Detected?	☐ Yes ☐ No ☐ Unknown	If molecular studies were performed for this patient, indicate whether molecular abnormalities were detected 3121579																																																																																				
82	Molecular Study Abnormalities <i>(Check all that apply)</i>	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 25%;">Test</th> <th style="width: 25%;">Negative</th> <th style="width: 25%;">Positive, %</th> <th style="width: 25%;">Not Tested</th> </tr> </thead> <tbody> <tr><td>BCR-ABL</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____%</td><td style="text-align: center;">☐</td></tr> <tr><td>PML-RAR</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____%</td><td style="text-align: center;">☐</td></tr> <tr><td>FLT3</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____%</td><td style="text-align: center;">☐</td></tr> <tr><td>FLT3 Mutation</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____%</td><td style="text-align: center;">☐</td></tr> <tr><td>IDH1 R132</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____%</td><td style="text-align: center;">☐</td></tr> <tr><td>IDH2 R140</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____%</td><td style="text-align: center;">☐</td></tr> <tr><td>IDH2 R172</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____%</td><td style="text-align: center;">☐</td></tr> <tr><td>Activating RAS</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____%</td><td style="text-align: center;">☐</td></tr> <tr><td>NPMc</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____%</td><td style="text-align: center;">☐</td></tr> <tr><td>KIT</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____%</td><td style="text-align: center;">☐</td></tr> <tr><td>CEBPA</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____%</td><td style="text-align: center;">☐</td></tr> <tr><td>PTPN11</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____%</td><td style="text-align: center;">☐</td></tr> <tr><td>MPL</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____%</td><td style="text-align: center;">☐</td></tr> <tr><td>JAK2</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____%</td><td style="text-align: center;">☐</td></tr> <tr><td>JAK3</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____%</td><td style="text-align: center;">☐</td></tr> <tr><td>RUNX1</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____%</td><td style="text-align: center;">☐</td></tr> <tr><td>GATA-1</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____%</td><td style="text-align: center;">☐</td></tr> <tr><td>MN1</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____%</td><td style="text-align: center;">☐</td></tr> <tr><td>ERG</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____%</td><td style="text-align: center;">☐</td></tr> <tr><td>Other</td><td style="text-align: center;">☐</td><td style="text-align: center;">_____%</td><td style="text-align: center;">☐</td></tr> </tbody> </table>	Test	Negative	Positive, %	Not Tested	BCR-ABL	☐	_____%	☐	PML-RAR	☐	_____%	☐	FLT3	☐	_____%	☐	FLT3 Mutation	☐	_____%	☐	IDH1 R132	☐	_____%	☐	IDH2 R140	☐	_____%	☐	IDH2 R172	☐	_____%	☐	Activating RAS	☐	_____%	☐	NPMc	☐	_____%	☐	KIT	☐	_____%	☐	CEBPA	☐	_____%	☐	PTPN11	☐	_____%	☐	MPL	☐	_____%	☐	JAK2	☐	_____%	☐	JAK3	☐	_____%	☐	RUNX1	☐	_____%	☐	GATA-1	☐	_____%	☐	MN1	☐	_____%	☐	ERG	☐	_____%	☐	Other	☐	_____%	☐	If molecular studies were performed for this patient, provide the outcome of the molecular abnormalities. If the outcome is positive, provide the percent positive for each abnormality. 3121628 and 3151753
Test	Negative	Positive, %	Not Tested																																																																																				
BCR-ABL	☐	_____%	☐																																																																																				
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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.

#	Data Element	Entry Alternatives	Working Instructions																																			
83	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																																						
84	Month of New Tumor Event	<table style="width: 100%;"> <tr> <td>☐ 01</td> <td>☐ 04</td> <td>☐ 07</td> <td>☐ 10</td> </tr> <tr> <td>☐ 02</td> <td>☐ 05</td> <td>☐ 08</td> <td>☐ 11</td> </tr> <tr> <td>☐ 03</td> <td>☐ 06</td> <td>☐ 09</td> <td>☐ 12</td> </tr> </table>	☐ 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																							
☐ 01	☐ 04	☐ 07	☐ 10																																			
☐ 02	☐ 05	☐ 08	☐ 11																																			
☐ 03	☐ 06	☐ 09	☐ 12																																			
85	Day of New Tumor Event	<table style="width: 100%;"> <tr> <td>☐ 01</td> <td>☐ 08</td> <td>☐ 14</td> <td>☐ 20</td> <td>☐ 26</td> </tr> <tr> <td>☐ 02</td> <td>☐ 09</td> <td>☐ 15</td> <td>☐ 21</td> <td>☐ 27</td> </tr> <tr> <td>☐ 03</td> <td>☐ 10</td> <td>☐ 16</td> <td>☐ 22</td> <td>☐ 28</td> </tr> <tr> <td>☐ 04</td> <td>☐ 11</td> <td>☐ 17</td> <td>☐ 23</td> <td>☐ 29</td> </tr> <tr> <td>☐ 05</td> <td>☐ 12</td> <td>☐ 18</td> <td>☐ 24</td> <td>☐ 30</td> </tr> <tr> <td>☐ 06</td> <td>☐ 13</td> <td>☐ 19</td> <td>☐ 25</td> <td>☐ 31</td> </tr> <tr> <td>☐ 07</td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	☐ 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
☐ 01	☐ 08	☐ 14	☐ 20	☐ 26																																		
☐ 02	☐ 09	☐ 15	☐ 21	☐ 27																																		
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☐ 07																																						
86	Year of New Tumor Event	_____	If the patient had a new tumor event, provide the year of diagnosis for this new tumor event. 3104046																																			
87	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>																																			

Acute Myeloid Leukemia (LAML)

#	Data Element	Entry Alternatives	Working Instructions
<u>88</u>	Type of New Tumor Event	☐ Locoregional ☐ 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
<u>89</u>	Site of New Tumor Event	☐ Bone Marrow ☐ Brain ☐ Lung ☐ Bone ☐ Liver ☐ Other, specify	Indicate the site of this new tumor event. 3108271
<u>90</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>91</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
<i>Date of Additional Surgery for New Tumor Event (when applicable)</i>			
<u>92</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. 3427612
<u>93</u>	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. 3427613
<u>94</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>95</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>
<u>96</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. 3427615
<u>97</u>	Additional treatment for New Tumor Event: <i>Pharmaceutical Therapy</i>	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received pharmaceutical treatment for this new tumor event. 3427616

Principal Investigator or Designee Signature

Print Name

Date