#### **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 If the answer to this question is yes, time intervals must be Has this TSS received provided instead of dates, as indicated throughout this form. permission from the Provided time intervals must begin with the date of initial NCI to provide time Yes 1 pathologic diagnosis (e.g. biopsy). intervals as a substitute □ No Only provide interval data if you have received permission from for requested dates on the NCI to provide time intervals as a substitute for requested this form? dates on this form. Indicate whether the TSS providing tissue is contracted for prospective tissue collection. If the submitted tissue was Is this a prospective □ Yes collected for the specific purpose of TCGA, the tissue has been 2 tissue collection? collected prospectively. □ No 3088492 Indicate whether the TSS providing tissue is contracted for retrospective tissue collection. If the submitted tissue was 🗖 Yes Is this a retrospective collected prior to the date the TCGA contract was executed, the 3 tissue collection? tissue has been collected retrospectively. □ No 3088528

#### **Patient Information**

#	Data Element		Entry Alternatives				Working Instructions
Date of Birth			•				
4	Month of Birth	□ 01 □ 02 □ 03	□ 04 □ 05 □ 06		07 08 09	□ 10 □ 11 □ 12	Provide the month the patient was born. <u>2896950</u>
5	Day of Birth	<ul> <li>01</li> <li>02</li> <li>03</li> <li>04</li> <li>05</li> <li>06</li> <li>07</li> </ul>	<ul> <li>08</li> <li>09</li> <li>10</li> <li>11</li> <li>12</li> <li>13</li> </ul>	<ul> <li>14</li> <li>15</li> <li>16</li> <li>17</li> <li>18</li> <li>19</li> </ul>	<ul> <li>20</li> <li>21</li> <li>22</li> <li>23</li> <li>24</li> <li>25</li> </ul>	□ 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. 2200604
9	Race	<ul> <li>American Indian or Alaska Native         <ul> <li>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.</li> </ul> </li> <li>Asian         <ul> <li>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.</li> </ul> </li> <li>White         <ul> <li>A person having origins in any of the original peoples of the far Europe, the Middle East, or North Africa.</li> </ul> </li> <li>Black or African American         <ul> <li>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."</li> <li>Native Hawaiian or other Pacific Islander:</li></ul></li></ul>	Provide the patient's race using the defined categories. 2192199
10	Ethnicity	<ul> <li>Not Hispanic or Latino: A person not meeting the definition of Hispanic or Latino.     </li> <li>Hispanic or Latino: A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race.     </li> <li>Not Evaluated: Not provided or available.     </li> <li>Unknown: Could not be determined or unsure.     </li> </ul>	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. <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.
12	History of Prior Hematologic Disorder	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient has a history of hematologic disorders. <u>3120971</u>
13	History of Neo-adjuvant Treatment for Sample Submitted for TCGA <i>(excluding hydroxyurea)</i>	□ Yes □ No	Indicate whether the patient received neo-adjuvant treatment (radiation, pharmaceutical, or both) prior to the collection of the sample submitted for TCGA. <u>3382737</u> 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.

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#	Data Element	Entry	y Alternatives		Working Instructions
	Did patient receive	□ Yes	,		Indicate whether the patient received hydroxyurea prior to
14	hydroxyurea <b>prior to</b>	🗖 No			procurement of the specimen submitted for TCGA. 3121638
	procurement?	🗖 Unknown			
	Days of Hydroxyurea				If the patient received hydroxyurea treatment prior to the procurement of the specimen submitted for TCGA, provide the
15	Treatment			-	number of days hydroxyurea was given.
					2724416
	Cumulative Dose of				If the patient received hydroxyurea treatment prior to the procurement of the specimen submitted for TCGA, provide the
16	Hydroxyurea		n	ng	cumulative dose of hydroxyurea administered.
	Treatment				<u>1515</u>
					Indicate whether the patient received ATRA (aka Vesanoid or
	Did patient receive	<b></b>			Tretinoin) prior to the procurement of the specimen submitted for TCGA. If the patient did receive this treatment
18	ATRA (aka Vesanoid or Tretinoin) treatment	□ Yes □ No			prior to procurement, this case will be excluded from TCGA.
	<i>prior to procurement</i> ?				<u>3121640</u>
	prior to procurement:				If the answer to this question is yes, this case will be excluded.
	Did patient receive				Indicate whether the patient received steroids prior to the procurement of the specimen submitted for TCGA. If the
	steroids for this	□ Yes			patient did receive this treatment prior to procurement, this
19	malignancy <i>prior to</i>				case will be excluded from TCGA.
	procurement?				<u>3121323</u>
	D		Pesticid		<i>If the answer to this question is yes, this case will be excluded.</i> Indicate whether the patient has a history of exposure to non-
	Previous Exposure to Non-Medical	☐ None ☐ Benzene	Unknow		medical potentially leukemogenic agents.
20	Potentially	Radiation	Difkilow		<u>3121309</u>
	Leukemogenic Agents		, - ,	F J	
	Other Chemical				If the patient was exposed to non-medical potentially
21	Exposure			-	leukemogenic agents and the type of exposure was not included in the provide list, specify the type of exposure.
					3131188
22	Vital Status	Living			Indicate whether the patient was living or deceased at the date of last contact.
22	(at date of last contact)	Deceased			<u>2939553</u>
Date	e of Last Contact (If patier	nt is living)			
				_	If the patient is living, provide the month of last contact with
22					the patient (as reported by the patient, medical provider, family member, or caregiver).
23	Month of Last Contact	$\begin{array}{c} \Box \ 02 \\ \Box \ 03 \end{array}  \Box \ 05 \\ \Box \ 06 \end{array}$	□ 08 □ 09	□ 11 □ 12	2897020
					Do not answer if patient is deceased.
		<b>□</b> 01 <b>□</b> 08	<b>□</b> 14 <b>□</b> 20	<b>2</b> 6	If the patient is living, provide the day of last contact with the
		<b>□</b> 02 <b>□</b> 09	<b>□</b> 15 <b>□</b> 21	<b>D</b> 27	patient (as reported by the patient, medical provider, family member, or caregiver).
				<b>2</b> 8	<u>2897022</u>
24	Day of Last Contact	□ 04 □ 11 □ 05 □ 12	□ 17 □ 23 □ 18 □ 24	□ 29 □ 30	
		$\Box 05 \qquad \Box 12 \\ \Box 06 \qquad \Box 13$	$\square 10 \qquad \square 24 \\ \square 19 \qquad \square 25 \\ \square 25 \\ \square 10 \\ $		Do not answer if patient is deceased.
				- 01	
					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).
25	Year of Last Contact			-	<u>2897024</u>
					Do not answer if patient is deceased.
					Provide the number of days from the date the patient was
	Number of Days from				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.
26	Date of Initial				initially diagnosed pathologically with the disease described
26	-			-	initially diagnosed pathologically with the disease described on this form to the date of last contact.

### **Enrollment Form** Acute Myeloid Leukemia (LAML)

#	Data Element	Entry Alternatives	Working Instructions
	e of Death		0
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. <u>2897026</u>
28	Day of Death	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	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. <u>3165475</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.
31	Radiation Therapy	☐ Yes □ No □ Unknown	Indicate whether the patient had radiation therapy <u>for</u> <u>the sample submitted for TCGA</u> . <u>IF the patient did have</u> <u>radiation, the Radiation Supplemental Form should be</u> <u>completed</u> . 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 <u>for the sample submitted for TCGA</u> . IF the patient did have pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed. <u>3397567</u>
34	Measure of success of outcome <u>at the</u> <u>completion of initial</u> <u>first course treatment</u>	<ul> <li>Persistent Disease</li> <li>Complete Remission</li> <li>Not Applicable</li> </ul>	Provide the patient's response to their initial first course treatment. 2786727
35	Performance Status Scale: Karnofsky Score	<ul> <li>100 - Normal, no complaints, no evidence of disease</li> <li>90 - Able to carry on normal activity; minor signs or symptoms of disease</li> <li>80 - Normal activity with effort; some signs or symptoms of disease</li> <li>70 - Cares for self, unable to carry on normal activity or to do active work</li> <li>60 - Requires occasional assistance, but is able to care for most of his/her needs</li> <li>50 - Requires considerable assistance and frequent medical care</li> <li>40 - Disabled, requires special care and assistance</li> <li>30 - Severely disabled, hospitalization indicated. Death is not imminent.</li> <li>20 - Very sick, hospitalization indicated. Death not imminent</li> <li>10 - Moribund, fatal processes progressing rapidly</li> <li>0 - Dead</li> <li>Unknown</li> <li>Not Evaluated</li> </ul>	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) (To be taken prior to surgery/treatment)	<ul> <li>0 - Asymptomatic</li> <li>1 - Symptomatic but fully ambulatory</li> <li>2 - Symptomatic but in bed less than 50% of the day</li> <li>3 - Symptomatic and in bed more than 50% of the day</li> <li>4 - Bedridden</li> <li>Unknown</li> <li>Not Evaluated</li> </ul>	Provide the patient's Eastern Cooperative Oncology Group (ECOG) score using the defined categories. This score represents the functional performance status of the patient. <u>88</u>
37	Performance Status Scale: Timing	<ul> <li>Induction</li> <li>Re-induction</li> <li>Consolidation</li> <li>Salvage</li> <li>Maintenance</li> <li>Other</li> <li>Unknown</li> <li>Not Applicable</li> </ul>	Provide a time reference for the Karnofsky score and/or the ECOG score using the defined categories. 2792763 If ECOG or Karnofsky Scores were not evaluated, select Not Applicable.
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. <u>3151756</u>

### 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. <u>2735776</u>
40	Source of Cells used for Analysis	<ul> <li>Bone Marrow Aspirate</li> <li>Peripheral Blood</li> </ul>	Using the laboratory report, provide the source of cells used for analysis. <u>64583</u>
Date	e and Method of Initial Pa	athologic Diagnosis	
41	Month of Initial Pathologic Diagnosis	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	Provide the month the patient was initially pathologically diagnosed with the malignancy submitted for TCGA. <u>2896956</u>
42	Day of Initial Pathologic Diagnosis	$\begin{array}{c c c c c c c c c c c c c c c c c c c $	Provide the day the patient was initially pathologically diagnosed with the malignancy submitted for TCGA. <u>2896958</u>
43	Year of Initial Pathologic Diagnosis		Provide the year the patient was initially pathologically diagnosed with the malignancy submitted for TCGA. <u>2896960</u>
44	Age at Initial Melanoma Diagnosis		<ul> <li>Provide the age of the patient in years, at the time the patient was initially pathologically diagnosed with melanoma.</li> <li><u>2006657</u></li> <li>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.</li> </ul>
45	Method of Initial Pathologic Diagnosis	<ul> <li>Core Biopsy</li> <li>Bone Marrow Aspirate</li> <li>Blood Draw</li> </ul>	Provide the procedure used to initially diagnose the patient. <u>2757941</u> Please note that this method is referring to the procedure performed on the Date of Initial Pathologic Diagnosis, provided in the previous question.
46	Percent Blasts Peripheral Blood at diagnosis	%	Using the pathology/laboratory report, provide the percent blasts in the peripheral blood. <u>58282</u>

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#	Data Element		Entry Alt	ernatives		Working Instructions
		Classifie	d by WHO only		V	Using the pathology/laboratory report, provide the patient's
		Biophen	otypic	🗖 M4		French American British (FAB) morphologic classification of leukemia. If the FAB classification is not available for this
4.7	FAB Category for Bone	🗖 M0 Undi	fferentiated	🗖 M4	eos	patient, provide the WHO classification below.
47	Marrow	<b>D</b> M1		🗖 M5		<u>3124352</u>
	(If available)	<b>—</b> M2		<b>D</b> M6		
		<b>M</b> 3		<b>D</b> M7		
			d by FAB Only			Using the pathology/laboratory report, provide the patient's
			h t(8;21)(q22;		RUNX1T1	World Health Organization classification, when available. If
		AML wit	h inv(16)(p13	q22) or t(16;	16)	the WHO classification is not available for this patient, provide the FAB classification above.
			22), (CBFβ/M			3257714
			h t(9;11)(p22;			<u>5257714</u>
			h t(6;9)(p23;q			
			h inv(3)(q21;c		3)	
			6.2);RPNI-EVI			
			gakaryoblasti		2)	
	AML World Health		3); RBM15-MH h mutated NPI			
48			h mutated NP			
48	Organization (WHO)		h minimal diff			
	(If available)		hout maturati			
			h maturation	011		
		Acute my	/elomonocytic	: leukemia		
			onoblastic/mc		mia	
			, ythroid leuker			
		Erythrol	eukemia, erytl	hroid/myeloi	d	
			egakaryoblast			
		Acute basophilic leukemia				
			nmyelosis wit			
			h myelodyspla		nanges	
		Test	Negative	Outcome	Not Tootod	Using the pathology/laboratory report, provide the patient's immunophenotype & cytochemistry results. If the test was
		NA	Negative	Positive, %	Not Tested	positive, provide the percent positive when available.
		MPX		%		<u>3121483</u> and <u>3121491</u>
		NSE		%		
		TDT		%		4
		CD3 CD4		%		
		CD4 CD5		%		
		CD7		/0		
		CD10		%		
		CD11c		%		4
		CD11d CD13		%		4
		CD13 CD14		%		1
		CD15		%		]
49	Immunophenotype &	CD19		%		4
	Cytochemistry	CD20		%		4
		CD23 CD25		%		4
		CD33		%		
		CD34		%		
		0001				
1		CD36		%		
		CD36 CD38		%		
		CD36 CD38 CD45		% %		
		CD36 CD38		%		
		CD36 CD38 CD45 CD56 CD64 CD65		<u>%</u> % % % %		
		CD36 CD38 CD45 CD56 CD64 CD65 CD79a		<u>%</u> % % % %		
		CD36 CD38 CD45 CD56 CD64 CD65 CD79a CD117		<u>%</u> <u>%</u> <u>%</u> <u>%</u> <u>%</u>		
		CD36 CD38 CD45 CD56 CD64 CD65 CD79a CD117 HLA-DR		<u>%</u> <u>%</u> <u>%</u> <u>%</u> <u>%</u>		
		CD36 CD38 CD45 CD56 CD64 CD65 CD79a CD117		<u>%</u> <u>%</u> <u>%</u> <u>%</u> <u>%</u>		

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#	Data Element	Entry Alternatives	Working Instructions
50	Percent (%) Cellularity	%	Using the patient's pathology/laboratory report, provide the percent cellularity. 58264
Con	plete Blood Count (Within	24 Hours of Banking)	<u>55251</u>
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
Diff	erential Count, Bone Marro	w (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. <u>2669786</u>
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. <u>3138062</u>
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

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70       Were Routine Cytogenetics Done?       INO       this patient.       2626417         71       Total Number of Metaphases       Image: State of the patient's pathology provide the total number of m 64523       Using the patient's pathology provide the total number of m 64523         72       Cytogenetic Risk Group (CALGB Criteria)       Image: Favorable Intermediate/Normal Intermediate/Normal Intermediate/Normal Image: Normal Intermediate/Normal Image: Normal Image: Norm	70	Were Routine			Indicate whether routine cytogenetic were performed for
70       Were Koutine Cytogenetics Done?       Invo       this patient. 2626417         71       Total Number of Metaphases       Image: Cytogenetic Risk Group (CALGB Criteria)       Favorable       Using the patient's pathology provide the total number of m 64523         72       Cytogenetic Risk Group (CALGB Criteria)       Favorable       Using the Cancer and Leukemia intermediate/Normal       Using the patient's laboratory re 3121502         73       Cytogenetic Analysis Abnormality Type (Check all that apply)       Image: One of the concert of the c	70	Were Routine			indicate whether routile cytogenetic were performed for
Cytogenetics Done?       Unknown       2626417         71       Total Number of Metaphases					
71       Total Number of Metaphases		Cytogenetics Done?			<u>2626417</u>
71       Total Number of Metaphases					Using the patient's pathology/laboratory report,
11       Metaphases	71	Total Number of			provide the total number of metaphases for this patient.
72     Cytogenetic Risk Group (CALGB Criteria)	/1	Metaphases			1 1 1
72       Cytogenetic Risk Group (CALGB Criteria)       Intermediate/Normal Poor       indicate the patient's cytogenetic 3121502         73       Approximation       Intermediate/Normal Poor       Normal       It(21;21)       Using the patient's laboratory re abnormalities found.         73       Abnormality Type (Check all that apply)       Intermediate/Normal       It(3;3)       It(15;17)       It(3;3)       It(15;17)         74       Abnormality Type (Check all that apply)       Intermediate/Normal       If the cytogenetic and they are not including in the abnormalities found.       If the cytogenetic abnormalities and they are not including in the abnormalities found.         74       Other Cytogenetic Analysis Abnormality Type       If the cytogenetic abnormalities and they are not including in the abnormalities found.       If the cytogenetic abnormalities and they are not including in the abnormalities found.         75       Was FISH Performed?       If yes       IffSH was not performed, the rel testing was performed for this p 64521.         76       Was FISH Abnormality Detected?       Indicate the patient's laboratory re abnormalities were found, provi         76       Was FISH Abnormality Detected?       If Yes       If fish testing was performed for this phormalities were found, provi         76       Was FISH Abnormality Detected?       Image: Second S					Using the Cancer and Leukemia Group B (CALGB) criteria,
72       Cytogenetic Risk Group (CALGB Criteria)       Intermediate/Normal Poor N/A - Remission       3121502         73       Name       Normal Normal       It(21;21) Inv(16)       Using the patient's laboratory real abnormalities found.         73       Abnormality Type (Check all that apply)       Inv(16) Inv(3)       It(8;21) It(3;3)       Using the patient's laboratory real abnormalities found.         74       Abnormality Type (Check all that apply)       Inv(3)       It(8;21)       It(8;21)         Inv(3)       It(3;3)       It(9;11)       It(9;22)       It(15;17)         Invision       Invision       It(9;22)       It(12;21)         Invision       It(4;11)       It(22;21)       It(12;21)         74       Other Cytogenetic Analysis Abnormality Type       It for cytogenetic abnormalities and they are not including in the abnormalities found.       It for cytogenetic abnormalities and they are not including in the abnormalities found.         75       Was FISH Performed?       Yes       Indicate whether Fluorescence I testing was performed for this p 64521         76       Was FISH Abnormality Detected?       Yes       If FISH testing was performed for whether abnormalities were foun 3121563         76       Was FISH Abnormality Detected?       Image: Sign Sign Sign Sign Sign Sign Sign Sign					indicate the patient's cytogenetic risk group.
(LALUB Criteria)       Poor         Image: N/A - Remission       Using the patient's laboratory realized inv(16)         Image: N/A - Remission       Using the patient's laboratory realized inv(16)         Image: N/A - Remission       Using the patient's laboratory realized inv(16)         Image: N/A - Remission       Using the patient's laboratory realized inv(16)         Image: N/A - Remission       Using the patient's laboratory realized inv(16)         Image: N/A - Remission       Using the patient's laboratory realized inv(16)         Image: N/A - Remission       Using the patient's laboratory realized inv(16)         Image: N/A - Remission       Using the patient's laboratory realized inv(16)         Image: N/A - Remission       Using the patient's laboratory realized inv(16)         Image: N/A - Remission       Using the patient's laboratory realized inv(16)         Image: N/A - Remission       Using the patient's laboratory realized inv(16)         Image: N/A - Remission       Using the patient's laboratory realized inv(16)         Image: N/A - Remission       Using the patient's laboratory realized inv(16)         Image: N/A - Remission       Using the patient's laboratory realized inv(16)         Image: N/A - Remission       Using the patient's laboratory realized inv(16)         Image: N/A - Remission       Image: N/A - Remission         Image: N/A - Remission       Image: N/A	72			al	3121502
73       Abnormality Type (Check all that apply)       Image: Normal methods of the second se		(CALGB Criteria)			
73       Not Tested       linv(16)       abnormalities found.         73       Cytogenetic Analysis       -5, del(5q) or t(5q)       tt(8;21)       2760451         73       Abnormality Type      5, del(5q) or t(5q)       tt(15;17)       2760451         74       Abnormality Type      7, del(7q) or t(7q)       Ddel(20q)			N/A – Remission		
73     Abnormality Type (Check all that apply)     Cytogenetic Analysis     Cytogenetic Analysis </td <td></td> <td></td> <td>Normal</td> <td><b>□</b>t(21;21)</td> <td>Using the patient's laboratory report, provide any cytogenetic</td>			Normal	<b>□</b> t(21;21)	Using the patient's laboratory report, provide any cytogenetic
73     Abnormality Type (Check all that apply)     Image: Cytogenetic Analysis Abnormality Type (Check all that apply)     Image: Cytogenetic Analysis Image: Cytogenetic Analysis Abnormality Type (Check all that apply)     Image: Cytogenetic Analysis Image: Cytogenetic Analysis Image: Cytogenetic Analysis Abnormality Type     Image: Cytogenetic Analysis Image: Cytogenetic Analysis Abnormality Type     Image: Cytogenetic Analysis Image: Cytogenetic Analysis Abnormality Type     If the cytogenetic abnormalities and they are not including in the abnormalities found. 2957553       75     Was FISH Performed?     Image: Cytogenetic Analysis Abnormality Type     Image: Cytogenetic Analysis Abnorma			□Not Tested	□inv(16)	
73       Immodia			□Complex	<b>□</b> t(6;9)	2760451
73       Cytogenetic Analysis Abnormality Type (Check all that apply)       I t(3;3)       It(9;11)         IIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIII					
Cytogenetic Analysis Abnormality Type (Check all that apply)       □-5, del(5q) or t(5q)       □t(15;17)       □del(20q)         □-7, del(7q) or t(7q)       □del(20q)       □+8       □-13 del(13q)         □+9       □(q22;q22)       □Trisomy 4       □3q         □del(17p)       □5q-       □t(4;11)       □7q-         □t(4;11)       □7q-       □t(9;22)       □Other, specify         74       Other Cytogenetic Analysis Abnormality Type       □Yes       Indicate whether Fluorescence I testing was performed for this p 64521         75       Was FISH Performed?       □Yes       Indicate whether Fluorescence I testing was performed for this p 64521         76       Was FISH Abnormality Detected?       □Yes       If FISH testing was performed for whether abnormalities were found 3121563         76       Was FISH Abnormality Detected?       □Yes       Indicate whether Fluorescence I testing was performed for whether abnormalities were found 3121563					
73       Abnormality Type (Check all that apply)       -7, del(7q) or t(7q)       del(20q)         +8       -13 del(13q)         +9       (q22;q22)         Trisomy 4       3q         del(17p)       5q-         tt(4;11)       7q-         tt(9;22)       Other, specify         74       Other Cytogenetic Analysis Abnormality Type       If the cytogenetic abnormalities and they are not including in the abnormalities found. 2957553         75       Was FISH Performed?       Yes         0       Yes         0       10 No         0       10 No         0       10 No         0       10 No         10 No       11 FISH testing was performed for this p 64521         11 FISH testing was performed for this p 64521         12 No       11 FISH testing was performed for this p 64521         13 No       12 If SISH was not performed, the rel 0 No         14 No       11 If SISH testing was performed for whether abnormalities were found 3121563         14 Marchan      %		Cytogenetic Analysis			
(Check all that apply)       +*8       -13 del[13q]         +*9       (q22;q22)         Trisomy 4       3q         del(17p)       5q-         t(4;11)       7q-         t(9;22)       00ther, specify         74       Analysis Abnormality         Type       Yes         Indicate whether Fluorescence I         vas FISH Performed?       Yes         Unknown       If FISH testing was performed for this p         64521       If FISH testing was performed for this p         01       No       3121563         76       Was FISH Abnormality       Yes         Unknown       If FISH testing was performed for whether abnormalities were found altower for the performed for this p         76       Was FISH Abnormality       Yes         Unknown       If FISH testing was performed for whether abnormalities were found altower for the performed for this p         76       PML-RAR      %	73			4 P	
1       1       +9       [](q22;q22)         1       1       1       3q         1       1       1       1         1       1       1       1         1       1       1       1         1       1       1       1         1       1       1       1       1         1       1       1       1       1         1       1       1       1       1         1       1       1       1       1         1       1       1       1       1       1         1       1       1       1       1       1       1         1					
4       3q       3q         1       1       1         74       0       0       1         74       0       0       1       1         74       0       0       1       1       1         74       0       0       1       1       1       1       1         74       0       0       1		(choon all chao apply)			
Image: Section of the section of th					
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74       Other Cytogenetic Analysis Abnormality Type       If the cytogenetic abnormalities and they are not including in the abnormalities found. 2957553         75       Was FISH Performed?       Yes       Indicate whether Fluorescence I testing was performed for this p 64521         76       Was FISH Abnormality Detected?       Yes       If FISH testing was performed for whether abnormalities were four 3121563         76       Was FISH Abnormality Detected?       Yes       If FISH testing was performed for whether abnormalities were four 3121563					
74       Analysis Abnormality Type       and they are not including in the abnormalities found. 2957553         75       Was FISH Performed?       Yes       Indicate whether Fluorescence It testing was performed for this performed for this performed, the reliver 0 Unknown         76       Was FISH Abnormality Detected?       Yes       If FISH testing was performed for whether abnormalities were found 3121563         76       BCR-ABL      %       If FISH testing was performed for abnormalities were found abnormalities were found abnormalities were found, provide abnormalities were found, provide		Oth or Cuto gon atio			If the cytogenetic abnormalities were found for this patient
Type     2957553       75     Was FISH Performed?     Yes     Indicate whether Fluorescence I testing was performed for this p       76     Was FISH Abnormality Detected?     Yes     If FISH testing was performed for whether abnormalities were four 3121563       76     BCR-ABL     %     If FISH testing was performed for abnormalities were four 3121563	74				and they are not including in the provided list, specify the
75       Was FISH Performed?       Yes       Indicate whether Fluorescence I testing was performed for this p         76       Was FISH Abnormality Detected?       Yes       If FISH testing was performed, the rel         8       Yes       If FISH testing was performed for this p         9       Was FISH Abnormality Detected?       Yes       If FISH testing was performed for whether abnormalities were formed for whether abnormalities were formed for abnormalitin formed formed for abnormalities were formed for abno	/4				
75       Was FISH Performed?       Image: Section of the sectin of the section of the secting section of th		Туре			
75       Was FISH Performed?       Image: No model of this performed for this performed, the relation of this performed for this performance formance for this performance for this performance			T Yes		Indicate whether Fluorescence In Situ Hybridization (FISH)
76     Was FISH Abnormality Detected?     Image: Constraint of the	75	Was FISH Performed?			
76       Was FISH Abnormality Detected?       Image: Constraint of the set of the s	/3	was i isii i citorineu:			<u>04521</u>
Was FISH Abnormality Detected?     Image: No Detected?     whether abnormalities were four 3121563       Image: No Detected?     Image: No Detected?     Image: No Detected?     Image: No Detected?     Image: No Detected?       Image: No Detected?     Image: No Detected?     Image: No Detected?     Image: No Detected?     Image: No Detected?       Image: No Detected?     Image: No Detected?     Image: No Detected?     Image: No Detected?     Image: No Detected?       Image: No Detected?     Image: No Detected?     Image: No Detected?     Image: No Detected?     Image: No Detected?       Image: No Detected?     Image: No Detected?     Image: No Detected?     Image: No Detected?     Image: No Detected?       Image: No Detected?     Image: No Detected?     Image: No Detected?     Image: No Detected?     Image: No Detected?       Image: No Detected?     Image: No Detected?     Image: No Detected?     Image: No Detected?     Image: No Detected?       Image: No Detected?     Image: No Detected?     Image: No Detected?     Image: No Detected?     Image: No Detected?       Image: No Detected?     Image: No Detected?     Image: No Detected?     Image: No Detected?     Image: No Detected?       Image: No Detected?     Image: No Detected?     Image: No Detected?     Image: No Detected?     Image: No Detected?       Image: No Detected?     Image: No Detected?     Image: No Detected					If FISH was not performed, the related questions can be skipped.
76     Detected?     I No     3121563       I Unknown     If FISH testing was performed for abnormalities were found, provided to the second sec		Was FISH Abnormality			If FISH testing was performed for this patient, indicate
BCR-ABL    %       PML-RAR    %	76				
PML-RAR% abnormalities were found, provi		2000000			
					If FISH testing was performed for this patient and FISH abnormalities were found, provide the percentages for each
MLL					5
СВРВ%					
For FISH Tested AML1-ETO %		For FISH Tested			4
77 Indicate %					4
(0.100) +8%					4
$\begin{array}{c c} -7 \text{ or } del(7q) & \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \$					1
$\frac{-5 \text{ of del(5q)}}{\text{del (20q)}} = \frac{-6}{3}\%$					1
Uter (200)        %           Other        %					
Total         100%					4
			Total	100 /0	Indicate whether molecular studies were performed for this
					patient.
nationt	70	Were other molecular			<u>3121565</u>
Were other molecular Ves 2121565	78				
78     Were other molecular     Yes     patient.       3121565		r i i r	Unknown		If other molecular studies were not performed, the related
78     Were other molecular studies performed?     Yes     patient.       1     No     Unknown					questions can be skipped.
78       Were other molecular studies performed?       Yes       patient.       3121565         No       Unknown       If other molecular studies were not questions can be skipped.			Southern		If molecular studies were performed for this patient, indicate
78       Were other molecular studies performed?       Yes       patient.       3121565         No       Unknown       If other molecular studies were not questions can be skipped.         Image: Southern       If molecular studies were performed?	70	Type of Molecular	□ RT-PCR		
78       Were other molecular studies performed?       Yes       patient.       3121565         No       Unknown       If other molecular studies were not questions can be skipped.         Type of Molecular       Southern       If molecular studies were performed the type of analysis that was down the type of analy	19	Analysis	Other, specify		<u>5121070</u>
78       Were other molecular studies performed?       Yes       patient.       3121565         10       No       Unknown       If other molecular studies were not questions can be skipped.         79       Type of Molecular       Southern       If molecular studies were perfor the type of analysis that was dor 3121575		-	Unknown		
78       Were other molecular studies performed?       Yes       patient.       3121565         No       Unknown       If other molecular studies were not questions can be skipped.         79       Type of Molecular Analysis       Southern       If molecular studies were performed analysis that was down analysis that was down analysis					If molecular studies were performed for this patient, and the
78       Were other molecular studies performed?       Yes       3121565         No       Unknown       If other molecular studies were not questions can be skipped.         79       Type of Molecular Analysis       Southern       If molecular studies were performed?         0       Unknown       0.00000000000000000000000000000000000	80	Other Type of Applyeic			type of analysis is not included in the provided list, specify the
78       Were other molecular studies performed?       Yes       3121565         No       Unknown       If other molecular studies were not questions can be skipped.         79       Type of Molecular Analysis       Southern       If molecular studies were performed?         0       Other Type of Analysis       Other, specify       If molecular studies were performed?         10       Other Type of Analysis       If molecular studies were performed?	00	outer Type of Allalysis			type of analysis done. 3151694

### **Enrollment Form** Acute Myeloid Leukemia (LAML)

#	Data Element		Entry Alt	ernatives		Working Instructions
81	Were Molecular Abnormalities Detected?	□ Yes □ No □ Unknow	<b>.</b>			If molecular studies were performed for this patient, indicate whether molecular abnormalities were detected <u>3121579</u>
		Test		Outcome		If molecular studies were performed for this patient, provide
			Negative	Positive, %	Not Tested	the outcome of the molecular abnormalities. If the outcome is positive, provide the percent positive for each abnormality.
		BCR-ABL		%		-3121628 and $3151753$
		PML-RAR		%		<u>5121020</u> and <u>5131735</u>
		FLT3		%		
		FLT3 Mutation		%		
		IDH1 R132		%		
		IDH2 R140		%		
		IDH2 R172		%		
	Molecular Study Abnormalities	Activating RAS		%		
82		NPMc		%		
	(Check all that apply)	KIT		%		
	(encon un chuc appig)	CEBPA		%		
		PTPN11		%		
		MPL		%		
		JAK2		%		
		JAK3		%		
		RUNX1		%		
		GATA-1		%		
		MN1		%		
		ERG		%		
		Other		%		

**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. <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>84</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>85</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>86</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>87</u>	Number of Days from Date of Initial Pathologic Diagnosis to Date of New Tumor Event After Initial Treatment		<ul> <li>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.</li> <li><u>3392464</u></li> <li>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.</li> </ul>

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# **Enrollment Form** Acute Myeloid Leukemia (LAML)

V4.07 043012

#	Data Element	Entry Alternatives		Working Instructions
<u>88</u>	Type of New Tumor Event	<ul> <li>Locoregional</li> <li>Distant Metastasis</li> <li>New Primary Tumor</li> </ul>		Indicate whether the patient's new tumor event was a locoregional recurrence, a distant metastasis or a new primary tumor. <u>3119721</u>
<u>89</u>	Site of New Tumor Event	<ul> <li>Bone Marrow</li> <li>Brain</li> <li>Lung</li> <li>Bone</li> <li>Liver</li> <li>Other, specify</li> </ul>		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. $\underline{3128033}$
<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
Date of Additional Surgery for New Tumor Event (when applicable)				
<u>92</u>	Month of Additional Surgery for New Tumor Event			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	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	□ 27 □ 28 □ 29 □ 30 □ 31	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). <u>3008335</u> Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested
<u>96</u>	Additional treatment for New Tumor Event: Radiation Therapy	☐ Yes ☐ No ☐ Unknown		dates on this form. Indicate whether the patient received radiation treatment for this new tumor event. <u>3427615</u>
<u>97</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