

Study Number:	AAML1031			
NCT #:	NCT01371981			
Dataset #:	D4			
PMID #:	32029509			
Subgroup (if applicable)	Patient level dataset			
Comments	Blanks represent missing data or not applicable for analyses. Data can be used to approximate published study findings, but exact reproduction of previous manuscripts may not be possible in some cases (e.g., when data must be modified for de-identification purposes or have undergone further data cleaning).			
Variable Number	Variable Name	Variable Type	Label	Note
1	usi	Char	USI	
2	consort_clsf	Char	Consort diagram classification	
3	trt_arm	Num	Treatment arm assignment at study entry	10='Arm A' 20='Arm B'
4	gender	Num	Gender	1='Male' 2='Female'
5	agecateg_	Num	Age category	1='0-1 year old' 2='2-10 years old' 3='11-15 years old' 4='16-20 years old' 5='>=21 years old'
6	ageyr	Num	Age at diagnosis in years	
7	race_cat	Num	Race category	1='American Indian or Alaska Native' 2='Asian' 3='Native Hawaiian or Other Pacific Islander' 4='Black or African American' 5='White' 6='Multiple Races' 9='Unknown'
8	raceb	Num	Race category- Black or non-black for known race	0='Non-black' 1='Black'
9	ethnic_cat	Num	Ethnicity category	1='Hispanic or Latino' 2='Not Hispanic or Latino' 3='Unknown'
10	wbc1	Num	WBC ( $\times 10^3/\mu\text{L}$ )	
11	wbc1_i	Num	Leukemic burden, WBC category	1='<=100,000/ $\mu\text{L}$ ' 2='>100,000/ $\mu\text{L}$ ' 3='Unknown'
12	cnsct_	Num	CNS disease classification at study entry	1='CNS1: < 5 WBC/ $\mu\text{L}$ of blood without blast cells' 2='CNS2: < 5 WBC/ $\mu\text{L}$ of blood with blast cells' 3='CNS3: >= 5 WBC/ $\mu\text{L}$ of blood with blast cells' 4='Unknown'

13	noncnsex	Num	Was the patient diagnosed with non-CNS extramedullary disease?	0='No' 1='Yes'
14	p2offtx_	Num	Is the patient off protocol therapy at the end of Induction II?	0='No' 1='Yes'
15	at821	Num	Abnormal karyotypes: t(8;21)	1='Positive' 2='Negative'
16	ainv16	Num	Abnormal karyotypes: Inv(16)/t(16;16)	1='Positive' 2='Negative'
17	cbf_pt	Char	CBF patient identification	
18	mll_pt	Char	MLL patient identification	
19	amono7	Num	Abnormal karyotypes: Monosomy 7	1='Positive' 2='Negative'
20	cyt5q_	Num	-5/5q-	1='Positive' 2='Negative'
21	itdlowHAR	Num	FLT3/ITD with low allelic ratio	1='Positive' 2='Negative'
22	npmstat_	Num	NPM	1='Positive' 2='Negative'
23	cebpast_	Num	CEBP $\alpha$	1='Positive' 2='Negative'
24	mrstat_	Num	MRD at end of Induction I	1='Positive' 2='Negative'
25	mrpct_pos	Num	MRD positive %	
26	riskgrp	Num	Risk group classification	10='Low risk' 30='High risk'

27	who_f	Num	WHO Classification	<p>193='AML with myelodysplasia-related changes'</p> <p>202='AML, not otherwise categorized'</p> <p>203='AML, not otherwise categorized: Acute erythroid leukemia (Erythroleukemia, erythroid/myeloid)'</p> <p>205='AML, not otherwise categorized: Acute erythroid leukemia (Pure erythroid leukemia)'</p> <p>206='AML, not otherwise categorized: AML without maturation'</p> <p>208='AML, not otherwise categorized: AML with maturation'</p> <p>209='AML, not otherwise categorized: AML with minimal differentiation'</p> <p>210='AML, not otherwise categorized: Acute myelomonocytic leukemia'</p> <p>212='AML, not otherwise categorized: Acute monoblastic/acute monocytic leukemia'</p> <p>216='AML, not otherwise categorized: Acute megakaryoblastic leukemia'</p> <p>250='AML with t(8;21)(q22;q22); RUNX1-RUNX1T1'</p> <p>252='AML with inv(16)(p13q22) or t(16;16)(p13;q22); CBFβ-MYH11'</p> <p>254='AML with t(9;11)(p22;q23); MLLT3-MLL'</p> <p>256='AML with t(6;9)(p23;q34); DEK-NUP214'</p> <p>258='AML with inv(3)(q21q26.2) or t(3;3)(q21;q26.2); RPN1-EVI1'</p> <p>260='AML (megakaryoblastic) with t(1;22)(p13;q13); RMB15-MKL1'</p> <p>262='AML with myelodysplasia-related changes'</p> <p>290='Provisional entity: AML with mutated CEBPA'</p> <p>292='Provisional entity: AML with mutated NPM1'</p> <p>480='Myeloid sarcoma'</p> <p>9999='Other'</p>
28	folup_yrs	Num	Years to last follow-up for patients alive at last contact	
29	yrsefs	Num	Years to EFS from study entry	
30	dysefs	Num	Days to EFS from study entry	

31	efsi	Num	EFS from study entry indicator	0='Censored' 1='EFS event'
32	yrsos	Num	Years to OS from study entry	
33	dysos	Num	Days to OS from study entry	
34	osi	Num	OS from study entry indicator	0='Alive at last contact (censored)' 1='Death'
35	yrscir	Num	Years to relapse/failure from study entry	
36	ciri	Num	CI to relapse/failure indicator	0='Censored' 1='Primary event (relapse/failure)' 2='Secondary event (death as first event)'
37	yrstrm_ons	Num	Years to TRM from study entry	
38	dystrm_ons	Num	Days to TRM from study entry	
39	trmi_ons	Num	TRM from study entry indicator	0='Censored' 1='Primary event (death as first event)' 2='Secondary event (relapse/failure)'
40	yrdfs1	Num	Years to DFS from end of Induction I for patients who continue on therapy	
41	dfsi1	Num	DFS from end of Induction I for patients who continue on therapy indicator	0='Censored' 1='DFS event'
42	yrsos1	Num	Years to OS from end of Induction I for patients who continue on therapy	
43	osi1	Num	OS from end of Induction I for patients who continue on therapy indicator	0='Alive at last contact (censored)' 1='Death'
44	yrscir1	Num	Years to relapse from end of Induction I for patients who continue on therapy	
45	ciri1	Num	CI to relapse from end of Induction I for patients who continue on therapy indicator	0='Censored' 1='Primary event (relapse/failure)' 2='Secondary event (death as first event)'
46	yrdfs2	Num	Years to DFS from end of Induction II for patients who continue on therapy	
47	dysdfs2	Num	Days to DFS from end of Induction II for patients who continue on therapy	
48	dfsi2	Num	DFS from end of Induction II for patients who continue on therapy indicator	0='Censored' 1='DFS event'
49	yrsos2	Num	Years to OS from end of Induction II for patients who continue on therapy	
50	dysos2	Num	Days to OS from end of Induction II for patients who continue on therapy	
51	osi2	Num	OS from end of Induction II for patients who continue on therapy indicator	0='Alive at last contact (censored)' 1='Death'

52	yrstrm2	Num	Years to TRM from end of Induction II for patients who continue on therapy	
53	dystrm2	Num	Days to TRM from end of Induction II for patients who continue on therapy	
54	trmi2	Num	TRM from end of Induction II for patients who continue on therapy indicator	0='Censored' 1='Primary event (death as first event)' 2='Secondary event (relapse/failure)'
55	yrstrr2	Num	Years to RR from end of Induction II for patients who continue on therapy	
56	dysrr2	Num	Days to RR from end of Induction II for patients who continue on therapy	
57	rri2	Num	RR from end of Induction II for patients who continue on therapy indicator	0='Censored' 1='Primary event (relapse)' 2='Secondary event (death as first event)'
58	trm_p1	Num	TRM event during Induction I for patients who received Induction I	0='No' 1='Yes'
59	trm_p2	Num	TRM event during Induction II for patients who received Induction II	0='No' 1='Yes'
60	trm_p3	Num	TRM event during Intensification I for patients who received Intensification I	0='No' 1='Yes'
61	trm_p4	Num	TRM event during Intensification II for patients who received Intensification II	0='No' 1='Yes'
62	trtarm_p1	Num	Treatment arm assignment during Induction I (eligible patients only for AE analysis)	10='Arm A' 20='Arm B'
63	card_hf_p1	Num	Heart failure - Induction I	0='No' 1='Yes'
64	card_ef_p1	Num	Ejection fraction decreased - Induction I	0='No' 1='Yes'
65	card_lvsd_p1	Num	Left ventricular systolic dysfunction - Induction I	0='No' 1='Yes'
66	nero_pnpn_p1	Num	Neuralgia, Paresthesia, Peripheral motor and sensory neuropathy - Induction I	0='No' 1='Yes'
67	nero_seiz_p1	Num	Seizure - Induction I	0='No' 1='Yes'
68	pulm_ards_p1	Num	Adult respiratory distress syndrome - Induction I	0='No' 1='Yes'
69	pulm_hypx_p1	Num	Hypoxia - Induction I	0='No' 1='Yes'
70	pulm_rf_p1	Num	Respiratory failure - Induction I	0='No' 1='Yes'
71	ren_kid_p1	Num	Acute kidney injury - Induction I	0='No' 1='Yes'

72	ren_creat_p1	Num	Creatinine increased - Induction I	0='No' 1='Yes'
73	p1_inf_vgs	Num	Microbiologically documented sterile site infection: Viridans group Streptococcus, at least one occurrence during Induction I	0='No' 1='Yes'
74	p1_inf_gnb	Num	Microbiologically documented sterile site infection: Gram Negative Bacilli, at least one occurrence during Induction I	0='No' 1='Yes'
75	p1_inf_fungi	Num	Microbiologically documented sterile site infection: Fungi, at least one occurrence during Induction I	0='No' 1='Yes'
76	p1doserd	Num	Dose reductions due to toxicity during Induction I?	0='No' 1='Yes'
77	p1icud	Num	ICU admission during Induction I?	0='No' 1='Yes'
78	p1efract	Num	Ejection fraction percentage - Induction I	
79	p1sfract	Num	Shortening fraction percentage - Induction I	
80	trt_arm_p2	Num	Treatment arm assignment during Induction II (eligible patients only for AE analysis)	10='Arm A' 20='Arm B'
81	card_hf_p2	Num	Heart failure - Induction II	0='No' 1='Yes'
82	card_ef_p2	Num	Ejection fraction decreased - Induction II	0='No' 1='Yes'
83	card_lvsd_p2	Num	Left ventricular systolic dysfunction - Induction II	0='No' 1='Yes'
84	nero_pnpn_p2	Num	Neuralgia, Paresthesia, Peripheral motor and sensory neuropathy - Induction II	0='No' 1='Yes'
85	nero_seiz_p2	Num	Seizure - Induction II	0='No' 1='Yes'
86	pulm_ards_p2	Num	Adult respiratory distress syndrome - Induction II	0='No' 1='Yes'
87	pulm_hypx_p2	Num	Hypoxia - Induction II	0='No' 1='Yes'
88	pulm_rf_p2	Num	Respiratory failure - Induction II	0='No' 1='Yes'
89	ren_kid_p2	Num	Acute kidney injury - Induction II	0='No' 1='Yes'
90	ren_creat_p2	Num	Creatinine increased - Induction II	0='No' 1='Yes'
91	p2_inf_vgs	Num	Microbiologically documented sterile site infection: Viridans group Streptococcus, at least one occurrence during Induction II	0='No' 1='Yes'

92	p2_inf_gnb	Num	Microbiologically documented sterile site infection: Gram Negative Bacilli, at least one occurrence during Induction II	0='No' 1='Yes'
93	p2_inf_fungi	Num	Microbiologically documented sterile site infection: Fungi, at least one occurrence during Induction II	0='No' 1='Yes'
94	p2doserd	Num	Dose reductions due to toxicity during Induction II?	0='No' 1='Yes'
95	p2icud	Num	ICU admission during Induction II?	0='No' 1='Yes'
96	p2efract	Num	Ejection fraction percentage - Induction II	
97	p2sfract	Num	Shortening fraction percentage - Induction II	
98	trt_arm_p3	Num	Treatment arm assignment during Intensification I (eligible patients only for AE analysis)	10='Arm A' 20='Arm B'
99	card_hf_p3	Num	Heart failure - Intensification I	0='No' 1='Yes'
100	card_ef_p3	Num	Ejection fraction decreased - Intensification I	0='No' 1='Yes'
101	card_lvsd_p3	Num	Left ventricular systolic dysfunction - Intensification I	0='No' 1='Yes'
102	nero_pnpn_p3	Num	Neuralgia, Paresthesia, Peripheral motor and sensory neuropathy - Intensification I	0='No' 1='Yes'
103	nero_seiz_p3	Num	Seizure - Intensification I	0='No' 1='Yes'
104	pulm_ards_p3	Num	Adult respiratory distress syndrome - Intensification I	0='No' 1='Yes'
105	pulm_hypx_p3	Num	Hypoxia - Intensification I	0='No' 1='Yes'
106	pulm_rf_p3	Num	Respiratory failure - Intensification I	0='No' 1='Yes'
107	ren_kid_p3	Num	Acute kidney injury - Intensification I	0='No' 1='Yes'
108	ren_creat_p3	Num	Creatinine increased - Intensification I	0='No' 1='Yes'
109	p3_inf_vgs	Num	Microbiologically documented sterile site infection: Viridans group Streptococcus, at least one occurrence during Intensification I	0='No' 1='Yes'
110	p3_inf_gnb	Num	Microbiologically documented sterile site infection: Gram Negative Bacilli, at least one occurrence during Intensification I	0='No' 1='Yes'

111	p3_inf_fungi	Num	Microbiologically documented sterile site infection: Fungi, at least one occurrence during Intensification I	0='No' 1='Yes'
112	p3doserd	Num	Dose reductions due to toxicity during Intensification I?	0='No' 1='Yes'
113	p3icud	Num	ICU admission during Intensification I?	0='No' 1='Yes'
114	p3efract	Num	Ejection fraction percentage - Intensification I	
115	p3sfract	Num	Shortening fraction percentage - Intensification I	
116	trt_arm_p4	Num	Treatment arm assignment during Intensification II (eligible patients only for AE analysis)	10='Arm A' 20='Arm B'
117	card_hf_p4	Num	Heart failure - Intensification II	0='No' 1='Yes'
118	card_ef_p4	Num	Ejection fraction decreased - Intensification II	0='No' 1='Yes'
119	card_lvsd_p4	Num	Left ventricular systolic dysfunction - Intensification II	0='No' 1='Yes'
120	nero_pnpn_p4	Num	Neuralgia, Paresthesia, Peripheral motor and sensory neuropathy - Intensification II	0='No' 1='Yes'
121	nero_seiz_p4	Num	Seizure - Intensification II	0='No' 1='Yes'
122	pulm_ards_p4	Num	Adult respiratory distress syndrome - Intensification II	0='No' 1='Yes'
123	pulm_hypx_p4	Num	Hypoxia - Intensification II	0='No' 1='Yes'
124	pulm_rf_p4	Num	Respiratory failure - Intensification II	0='No' 1='Yes'
125	ren_kid_p4	Num	Acute kidney injury - Intensification II	0='No' 1='Yes'
126	ren_creat_p4	Num	Creatinine increased - Intensification II	0='No' 1='Yes'
127	p4_inf_vgs	Num	Microbiologically documented sterile site infection: Viridans group Streptococcus, at least one occurrence during Intensification II	0='No' 1='Yes'
128	p4_inf_gnb	Num	Microbiologically documented sterile site infection: Gram Negative Bacilli, at least one occurrence during Intensification II	0='No' 1='Yes'
129	p4_inf_fungi	Num	Microbiologically documented sterile site infection: Fungi, at least one occurrence during Intensification II	0='No' 1='Yes'



<b>130</b>	p4doserd	Num	Dose reductions due to toxicity during Intensification II?	0='No' 1='Yes'
<b>131</b>	p4icud	Num	ICU admission during Intensification II?	0='No' 1='Yes'
<b>132</b>	p4efract	Num	Ejection fraction percentage - Intensification II	
<b>133</b>	p4sfract	Num	Shortening fraction percentage - Intensification II	
<b>134</b>	rem_response	Num	Remission status by end of Induction II	1='Complete response' 2='Not in complete response' 3='Not evaluable'
<b>135</b>	rcv_bortz_notif	Char	Identified patient on bortezomib arm who was informed to switch to standard chemotherapy arm after higher incidence of non-fatal treatment-related toxicities were discovered	
<b>136</b>	path_rev	Char	Centrally reviewed pathological findings available?	
<b>137</b>	cyto_rev	Char	Centrally reviewed cytogenetic findings available?	