

Dictionary AAML0431

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<i>For various reasons, data may contain slight discrepancies from that reported in the publication.</i>				
Variable number	Variable name	Variable Type	Label	Note
1	USI	Character	USI	
2	study	Character	Study category	
3	studya	Character	Study category (all patients)	
4	eligpt	Character	Study eligible? (AAML0431 only)	
5	sex	Character	Sex	
6	age_yrs	Numeric	Age in years from diagnosis	
7	wbc1	Numeric	WBC x10 ³ /MicroL	
8	perblsts	Numeric	Peripheral blasts (%)	
9	plt	Numeric	Hematology Platelet Lab Specified Value x10 ³ /MicroL	
10	pttmd	Character	Does patient have a history of TMD (Transient Myeloproliferative Disorder)?	
11	midsid	Character	AML/MDS	
12	race_a2971	Character	Race/Ethnicity (A2971 collection definition)	
13	trm_desc	Character	Treatment-related mortality description	
14	osi	Numeric	Overall survival from study entry indicator	0-censor, 1-death
15	ysos	Numeric	Years to overall survival from study entry	
16	efsi	Numeric	Event free survival from study entry indicator	0-censor, 1-event
17	yrsefs	Numeric	Years to event free survival from study entry	
18	consort_clsf	Character	AAML0431 consort diagram classification	
19	pmorph	Character	Primary morphology of the patient's AML	
20	ptrchm	Character	Has patient received chemotherapy intervention for TMD?	
21	mrd28_	Character	MRD status at day 28	
22	RACE_CAT	Character	Race category	
23	ETHNIC_CAT	Character	Ethnicity category	
24	folup	Numeric	Follow-up time (in years) for patients alive at last contact	
25	normal_	Character	Normal (trisomy 21 only): primary cytogenetic classification	
26	mono7_	Character	Monosomy 7: primary cytogenetic classification	
27	plus8_	Character	+8: primary cytogenetic classification	
28	osi1f	Numeric	Overall survival from refractory/relapse/SMN event indicator	0-censor, 1-death

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Variable number	Variable name	Variable Type	Label	Note
29	yrsos1f	Numeric	Years to overall survival from refractory/relapse/SMN event	
30	rri	Numeric	Cumulative incidence to relapse from study entry indicator	0-censor, 1-event, 2-competing event
31	yrsrr	Numeric	Years to cumulative incidence to relapse from study entry	
32	osi1d28	Numeric	Overall survival from day 28 BM indicator	0-censor, 1-death
33	yrsos1d28	Numeric	Years to overall survival from day 28 MRD	
34	dfsi1d28	Numeric	Disease free survival from day 28 MRD indicator	0-censor, 1-event
35	yrsdfs1d28	Numeric	Years to disease free survival from day 28 MRD	
36	Ind1_data	Character	Induction I data available	
37	Ind2_data	Character	Induction II data available	
38	Ind3_data	Character	Induction III data available	
39	Ind4_data	Character	Induction IV data available	
40	Int1_data	Character	Intensification I data available	
41	Int2_data	Character	Intensification II data available	
42	tmanc1	Numeric	Days to ANC recovery (Induction I)	
43	tmanc2	Numeric	Days to ANC recovery (Induction II)	
44	tmanc3	Numeric	Days to ANC recovery (Induction III)	
45	tmanc4	Numeric	Days to ANC recovery (Induction IV)	
46	tmanc5	Numeric	Days to ANC recovery (Intensification I)	
47	tmanc6	Numeric	Days to ANC recovery (Intensification II)	
48	p1icu_adm	Character	ICU admission (Induction I)	
49	p2icu_adm	Character	ICU admission (Induction II)	
50	p3icu_adm	Character	ICU admission (Induction III)	
51	p4icu_adm	Character	ICU admission (Induction IV)	
52	p5icu_adm	Character	ICU admission (Intensification I)	
53	p6icu_adm	Character	ICU admission (Intensification II)	
54	cong_heart	Character	Congenital heart defect?	
55	smn_pt	Character	SMN (B-precursor ALL) patient?	
56	smn_tm	Numeric	Time (in days) to SMN from off protocol therapy	
57	fabmcl	Character	FAB groups	
58	ind1_resp	Character	Induction I response	

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59	p1_infc1_	Character	Any sterile site Bacterial infection grade >=3? (Induction I)	
60	p2_infc1_	Character	Any sterile site Bacterial infection grade >=3? (Induction II)	
61	p3_infc1_	Character	Any sterile site Bacterial infection grade >=3? (Induction III)	
62	p4_infc1_	Character	Any sterile site Bacterial infection grade >=3? (Induction IV)	
63	p5_infc1_	Character	Any sterile site Bacterial infection grade >=3? (Intensification I)	
64	p6_infc1_	Character	Any sterile site Bacterial infection grade >=3? (Intensification II)	
65	p1_febntp	Character	Febrile neutropenia, Grade >=3, during Induction I	
66	p2_febntp	Character	Febrile neutropenia, Grade >=3, during Induction II	
67	p3_febntp	Character	Febrile neutropenia, Grade >=3, during Induction III	
68	p4_febntp	Character	Febrile neutropenia, Grade >=3, during Induction IV	
69	p5_febntp	Character	Febrile neutropenia, Grade >=3, during Intensification I	
70	p6_febntp	Character	Febrile neutropenia, Grade >=3, during Intensification II	
71	reptox_ind2	Character	Patient having at least one grade 3 reportable AE for reporting? (during Induction II)	
72	path_rev	Character	Pathology reviewed	
73	path_cls	Character	Pathology classification	
74	scr_pt	Character	Structural chromosome rearrangements?	
75	scr_bal	Character	Among structural chromosome rearrangements	
76	chrms1	Character	Gain from chromosome 1?	
77	chrms7	Character	Loss of material from short arm and/or long arm of chromosome 7?	
78	chrms11	Character	Gain of material from long arm of chromosome 11?	
79	chrms21	Character	Gain of fourth copy of chromosome 21?	
80	trisomy11	Character	Trisomy 11 status	
81	trisomy19	Character	Trisomy 19 status	
82	isoltri	Character	Isolated trisomy	
83	aplus8_	Character	Trisomy 8 status	
84	mrdresp	Character	MRD day 28, BM response day 28	

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Variable number	Variable name	Variable Type	Note
85	mrd28avail	Character	Day 28 MRD result available
86	cyto_clsfc	Character	Cytogenetics classification
87	ind1_rsp_day28i	Character	Induction day 28 response
88	bmresd14	Character	BM results at day 14 used instead of day 28 for Induction response?
89	dthonly	Character	AAML0431 patient: Infection related death without a failure/relapse
90	org_01	Character	Coagulase negative Staphylococcus (Induction II only)
91	org_02	Character	Enterococcus nos (Induction II only)
92	org_03	Character	Enterococcus faecalis (Induction II only)
93	org_04	Character	Staphylococcus nos (Induction II only)
94	org_05	Character	Staphylococcus aureus (Induction II only)
95	org_06	Character	Staphylococcus epidermidis (Induction II only)
96	org_07	Character	Staphylococcus hominis (Induction II only)
97	org_08	Character	Streptococcus nos (Induction II only)
98	org_09	Character	Streptococcus mitis (Induction II only)
99	org_10	Character	Streptococcus pneumoniae (Induction II only)
100	org_11	Character	Streptococcus sanguis (Induction II only)
101	org_12	Character	Viridans group streptococcus (Induction II only)
102	org_13	Character	Propionibacterium acnes (Induction II only)
103	org_14	Character	Aeromonas nos (Induction II only)
104	org_15	Character	Bacteroides nos (Induction II only)
105	org_16	Character	Capnocytophaga nos (Induction II only)
106	org_17	Character	Enterobacter cloacae (Induction II only)
107	org_18	Character	Escherichia coli (Induction II only)
108	org_19	Character	Fusobacterium nos (Induction II only)
109	org_20	Character	Fusobacterium nucleatum (Induction II only)
110	org_21	Character	Klebsiella nos (Induction II only)
111	org_22	Character	Proteus mirabilis (Induction II only)
112	org_23	Character	Pseudomonas aeruginosa (Induction II only)
113	org_24	Character	Pseudomonas fluorescens (Induction II only)
114	org_25	Character	Pseudomonas putida (Induction II only)
115	org_26	Character	Stenotrophomonas nos (Induction II only)
116	p2_mucos	Character	Mucositis oral Adverse Event, Grade >= 3 (Induction II)

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117	card_evnt1_int2	Character	Cardiac event: Prolonged QT-1, Grade 3 (Intensification II)	
118	card_evnt1_int1	Character	Cardiac event: Cardiac arrest, Grade 4 (Intensification I)	
119	card_evnt1_ind2	Character	Cardiac event: Sinus tachycardia, Grade 3 (Induction II)	
120	card_evnt1_ind1	Character	Cardiac event: Pericardial effusion, Grade 3 (Induction I)	
121	card_evnt2_ind2	Character	Cardiac event: Pericardial effusion, Grade 3 (Induction II)	
122	card_evnt2_int1	Character	Cardiac event: Pericardial effusion, Grade 4 (Intensification I)	
123	card_evnt2_ind1	Character	Cardiac event: Sinus tachycardia, Grade 3 (Induction I)	
124	totalAEs_ind1	Numeric	Total number of submitted AEs (Induction I only)	
125	totalAEs_ind2	Numeric	Total number of submitted AEs (Induction II only)	
126	totalAEs_ind3	Numeric	Total number of submitted AEs (Induction III only)	
127	totalAEs_ind4	Numeric	Total number of submitted AEs (Induction IV only)	
128	totalAEs_int1	Numeric	Total number of submitted AEs (Intensification I only)	
129	totalAEs_int2	Numeric	Total number of submitted AEs (Intensification II only)	
130	totalAEs_fup	Numeric	Total number of submitted AEs (Follow-up only)	
131	totalAEs	Numeric	Total number of submitted AEs	
132	totalAEs_gr4_ind2	Numeric	Total number of submitted AEs, grade 4 only (Induction II only)	
133	ind2_grd3h_AE	Character	Having at least 1 grade 3 or higher AE submitted during Induction II	
134	GATA1	Character	GATA1 mutation result	
135	trtfail_rsn	Character	Treatment failure reason	
136	smn_pt_desc	Character	SMN development description	
137	mrd28avail_desc	Character	MRD day 28 description	
138	mrdlevc_desc	Character	MRD day 28 percentage level description	
139	sct_descr	Character	SCT description	
140	mrd4_	Character	MRD status at end of Ind IV	