Study Number:	AALL0434
NCT #:	NCT00408005
Dataset #:	NCT00408005-D4
PMID #:	32813610
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Variable Number	Variable Name	Variable Type	Label	Notes
1	USI	Character	Unique patient identifier	
2	type	Character	Disease type	
3	inelig	Character	Indicates patient is ineligible for AALL0434	Yes = Not eligible; Blank = Eligible
4	inevaluable_study	Character	Indicates patient is inevaluable for AALL0434 (if not inelig)	Yes = Not evaluable Blank = Evaluable
5	inevaluable_post	Character	Indicates patient is inevaluable for post-induction (if not inelig and not inevaluable_study)	Yes = Not evaluable post-induction; Blank = Evaluable post-induction
6	off_therapy_eoi	Numeric	Indicates patient is off therapy at the End of Induction (if not inelig and not inevaluable_study and not inevaluable_post)	1 = Yes; Blank = Not off therapy at the End of Induction

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Variable Number	Variable Name	Variable Type	Label	Notes
7	stratumid	Numeric	Enrollment stratum	20=Low Risk - All Other Patients; 22= Low Risk - Seizure Disorder/Pre-existing Peripheral Neurotoxicity (No Down Syndrome); 30=Intermediate Risk – All other patients (Safety Phase); 32=Intermediate Risk – Seizure Disorder/Pre-existing Peripheral Neurotoxicity, No Down Syndrome (Safety Phase); 33=Intermediate Risk – CNS3 and/or Testicular Disease, No Down Syndrome (Safety Phase); 40=Intermediate Risk – All other patients (Efficacy Phase); 42=Intermediate Risk – Seizure Disorder/Pre-existing Peripheral Neurotoxicity, No Down Syndrome (Efficacy Phase); 43=Intermediate Risk – CNS3 and/or Testicular Disease, No Down Syndrome (Efficacy Phase); 50=High Risk – All other patients; 51=High Risk – Down Syndrome; 52=High Risk – Seizure Disorder/Pre-existing Peripheral Neurotoxicity, No Down Syndrome; 53=High Risk – CNS3 and/or Testicular Disease, No Down Syndrome; 60=M3 Marrow end of Induction (No Down Syndrome, No Seizure Disorder, No Pre-existing Peripheral Neurotoxicity);

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Variable Number	Variable Name	Variable Type	Label	Notes
8	off_reason	Character	Reasons off protocol therapy at the End of Induction	
9	ineval_rsn	Character	Reasons inevaluable	
10	inelig_reason	Character	Reasons ineligible	
11	nel_rand	Numeric	Subjects randomized to Nelarabine	1=Yes, patient randomized to receive or not receive nelarabine; 0=No, patient not randomized to receive or not receive nelarabine
12	arm	Character	Treatment Arm	
13	risk	Character	Risk group	0=Off therapy at End of Induction; 1=Low Risk; 2=Intermediate Risk; 3=High Risk; 4=M3 marrow end of induction
14	hsct	Numeric	Indicates patient received allogeneic hematopoietic stem-cell transplantation (alloHSCT)	1=Yes; 0=No
15	etp_status	Numeric	Early T-precursor (ETP) Status	1=ETP; 2=No ETP;3=Near ETP
16	etp_near	Numeric	Early T-precursor (ETP) Status grouped	0=No ETP; 1=ETP or Near ETP
17	age_16	Character	Age group	
18	gender	Character	Gender	
19	race_cat	Character	Race	
20	race	Character	Race group	
21	ethnic_cat	Character	Ethnicity	
22	wbc_cat	Character	White blood cells category (x10^3/MicroLiter)	

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Variable Number	Variable Name	Variable Type	Label	Notes
23	cns	Numeric	Central nervous system status	1=CNS 1; 2=CNS 2; 3=CNS 3
24	bm_day29	Numeric	Bone marrow status at end of Induction	1=M1: <5% lymphoblasts; 2=M2: 5-25% lymphoblasts; 3=M3:>25% lymphoblasts
25	mrd_cat	Numeric	Minimal Residual Disease (MRD) percentage at End Induction (%)	1=MRD<0.01%; 2=0.01%<=MRD<0.1%; 3=0.1%<=MRD<1.0%; 4=1.0%<=MRD<10.0%; 5=MRD>=10%
26	nel	Character	Patients randomized to receive nelarabine or not (if Nel_rand = 1)	
27	mtx	Character	Methotrexate received (HD-MTX versus C-MTX)	
28	x1_updated	Numeric	Event-Free survival time (days)	
29	x2_updated	Numeric	Event-Free survival status	1=Had event; 0=Censored
30	surv_x1_updated	Numeric	Overall survival time (days)	
31	surv_x2_updated	Numeric	Overall survival status	1=Death; 0=Censored
32	ccr_x1_updated	Numeric	Disease-Free survival time (days)	
33	ccr_x2_updated	Numeric	Disease-Free survival status	1=Had event; 0=Censored
34	event	Character	First event type	
35	site_of_relapse	Character	Relapse site	

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Variable Number	Variable Name	Variable Type	Label	Notes
36	eoi_rand_elig	Numeric	Indicates patient eligible for nelarabine randomization but did not participate	1=eligible for randomization but did not participate; 2=nelarabine randomized patients
37	smn_type	Character	Second Malignant Neoplasms subtype	
38	failure_type	Numeric	Event type to calculate cumulative incidence	0=No event; 1=CNS relapse; 2=Other relapse; 3=SMN; 4=Remission Death
39	m3_x1	Character	Event-Free survival time (days) for M3 patients	(Used to reproduce 5-year EFS for patients who experienced IF under "Risk-Stratified Outcomes" section)
40	m3_x2	Numeric	Event-Free survival status for M3 patients	1=Had event; 0=Censored (Used to reproduce 5-year EFS for patients who experienced IF under "Risk-Stratified Outcomes" section)
41	infection_tox	Numeric	Patients experienced central infectious toxicities	1=Yes; 0=No
42	central_tox	Numeric	Patients experienced central neurologic toxicities	1=Yes; 0=No
43	grade_central	Numeric	Grade of central neurologic toxicities	
44	motor_tox	Numeric	Patients experienced peripheral motor neuropathy	1=Yes; 0=No
45	grade_motor	Numeric	Grade of peripheral motor neuropathy	

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Variable Number	Variable Name	Variable Type	Label	Notes
46	sensor_tox	Numeric	Patients experienced peripheral sensory neuropathy	1=Yes; 0=No
47	grade_sensor	Numeric	Grade of peripheral sensory neuropathy	
48	x1_m3_hsct	Numeric	Event-Free survival time (days) of M3 patients for allogeneic hematopoietic stem-cell transplantation (alloHSCT) at investigator Discretion	(Used to reproduce Table 3 - row 3, under "AlloHSCT at Investigator Discretion" section)
49	x2_m3_hsct	Numeric	Event-Free survival status of M3 patients for allogeneic hematopoietic stem-cell transplantation (alloHSCT) at investigator Discretion	1=Had event; 0=Censored (Used to reproduce Table 3 - row 3, under "AlloHSCT at Investigator Discretion" section)
50	day_trans	Numeric	Stem Cell Transplant time (days) from enrollment	