

AALL0434, NCT00408005 D1

PMID 30138085

Blanks in the data set represent missing data

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	Description
1	usi	Character	USI ID	
2	type	Character	Disease type	
3	stratumid	Numeric	Stratum	1=All T-ALL patients at study entry; 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; 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); 70=All T-NHL patients at study entry; 71=Standard Risk T-NHL; 72=High Risk T-NHL; 73=Induction Failure T-NHL;

4	trt	Numeric	Treatment	1=Standard Induction - All Patients at Study Entry; 2=Arm A - Augmented BFM with Capizzi MTX, no Nelarabine (CMTX); 3=Arm B - Augmented BFM with Capizzi MTX plus Nelarabine (CMTX + Nel); 4=Arm C - Augmented BFM with High Dose MTX, no Nelarabine (HDMTX); 5=Arm D - Augmented BFM with High Dose MTX plus Nelarabine (HDMTX + Nel)
5	Elig	Numeric	Eligibility of the study	0=No; 1=Yes
6	inelig_reason	Character	reason of ineligible for study	
7	inevaluable_study	Numeric	Inevaluable for induction	0=No; 1=Yes
8	ineval_reason	Character	reason of inevaluable for induction	
9	elig_eval_tall	Numeric	Eligible, evaluable T-ALL patients for Induction and included for overall EFS/OS outcome analysis (N=1562)	0=No; 1=Yes
10	inevaluable_post	Numeric	inevaluable for post induction	0=No;1=Yes
11	off_therapy_eoi	Numeric	Whether patients went off therapy at the end of induction(EOI)	0=No;1=Yes
12	randomized_pt	Numeric	Subjects randomized to Methotrexate (HD-MTX versus C-MTX) and included for DFS outcome analysis (N=1031)	0=No; 1=Yes
13	risk	Character	Risk group	
14	age	Numeric	Age at diagnosis (years)	
15	age_cat	Numeric	age category	1=Age<10 years ;2=10 years <=Age<21 years;3=Age>=21 years
16	age_cat2	Numeric	age category	0=Age<15 years ;1=Age>=15 years
17	gender	Character	Gender	

18	race_cat	Numeric	Race	1=American Indian or Alaska Native; 2=Asian; 3=Native Hawaiian or other Pacific Islander; 4=Black or African American; 5=White; 9=Unknown
19	ethnic_cat	Numeric	Ethnicity	1=Hispanic or Latino; 2=Not Hispanic or Latino; 3=Unknown
20	wbc	Numeric	Number of white blood cells (x10 ³ /MicroLiter)	
21	wbc_cat	Numeric	white blood cells category (x10 ³ /MicroLiter)	1=wbc<50 ; 2=wbc>=50
22	cns	Numeric	Central nervous system status	1=CNS 1; 2=CNS 2; 3=CNS 3
23	BM_day29	Numeric	Bone marrow status at end of induction	1=M1: <5% lymphoblasts; 2=M2: 5-25% lymphoblasts 3=M3:>25% lymphoblasts
24	mrd_cat	Numeric	Minimal Residual Disease (MRD) percentage at end of 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%
25	death_induction	Numeric	death at induction or remission	1=Induction death;2=Remission Death
26	mtx	Character	Subjects randomized to Methotrexate (HD-MTX versus C-MTX)	
27	event_type	Numeric	Type of events	0=None; 1=Induction Failure; 2=Induction Death; 2.5=Progression;3=Relapse; 4=SMN; 5=Death; 103=Relapse (off-therapy); 104=SMN (off-therapy); 105=Death (off-therapy)
28	x2	Numeric	Event-free survival (EFS) event indicator	0=No event; 1=Had event
29	x1	Numeric	EFS time (days)	
30	surv_x2	Numeric	Overall survival (OS) event indicator	0=alive; 1=death
31	surv_x1	Numeric	OS time (days)	
32	ccr_x1_cns3	Numeric	Disease-Free survival (DFS) time (days) for CNS3 patients	
33	ccr_x2_cns3	Numeric	DFS event indicator for CNS3 patients	0=No event; 1=Had event

34	surv_x1_cns3	Numeric	Overall survival (OS) time (days) for CNS3 patients	
35	surv_x2_cns3	Numeric	OS event indicator for CNS3 patients	0=alive; 1=death
36	ccr_x1_testi	Numeric	Disease-Free survival (DFS) time (days) for testicular disease patients	
37	ccr_x2_testi	Numeric	DFS event indicator for testicular disease patients	0=No event; 1=Had event
38	surv_x1_testi	Numeric	Overall survival (OS) time (days) for testicular disease patients	
39	surv_x2_testi	Numeric	OS event indicator for testicular disease patients	0=alive; 1=death
40	rer	Numeric	Determine response	1=Rapid early responder (RER); 2=Slow early responder (SER)
41	os_time	Numeric	OS time (days) (from date of start consolidation to date of death or date of last contact)	
42	ccr_x2	Numeric	Disease-free survival (DFS) event indicator	0=No event; 1=Had event
43	ccr_x1	Numeric	DFS time (days)	
44	event_type_dfs	Numeric	Type of DFS events	0=None; 3.01=Relapse: Marrow; 3.02=Relapse: CNS; 3.03=Relapse: Marrow+CNS; 3.04=Relapse: Marrow+other relapse; 3.05=Relapse: Other; 4=SMN; 5=Death;
45	smn_type	Character	Second Malignant Neoplasms subtype	