Study Number:	ARST0531
NCT #:	NCT00354835
Dataset #:	D1
PMID #:	30091945

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Variable Number	Variable Name	Variable Type	Label	Note
1	USI	Character	Patient USI ID	
2	STUDY	Character	Protocol Number	
3	EligPtTc	Character	Is the patient eligible?	
4	Treatment	Character	ARST0531 treatment	
5	GENDER	Character	Gender	
6	AGE	Numeric	Age (in years) at date of diagnosis	
7	RACE	Character	Race	
8	ETHNICITY	Character	Ethnicity	
9	HISTOLOGY	Character	Type of rhabdomyosarcoma	
10	GROUP	Character	IRS (Intergroup Rhabdomyosarcoma Study) group	
11	STAGE	Numeric	IRS (Intergroup Rhabdomyosarcoma Study) stage	
12	MEASUREMENT	Numeric	Maximum diameter of tumor (cm)	
13	INVASIVE	Character	T stage	
14	LYMPH_NODE	Character	Regional lymph node status	
15	pri_site	Character	Primary site	
16	last_RP	Character	The reporting period when patient went off protocol therapy	
17	DxHepPPrt	Character	Was the patient diagnosed with hepatopathy per protocol?	
18	HepPthCtcae3Gd	Character	If patient experienced hepatopathy, the hepatopathy grade	
19	RP_hepatopathy	Character	The reporting period when the patient experienced hepatopathy	
20	event_type	Character	Type of first event	
21	EFS_EVENT	Numeric	Censoring flag for event. 0=Patient is censored (no event); 1=Patient had an event, i.e., relapse, progression, secondary malignancy, or death from any cause	
22	EFS_TIME	Numeric	Time (in days) from enrollment to first event, or to last contact if no event occurred	
23	OS_EVENT	Numeric	Censoring flag for death. 0=Patient is censored (no death); 1=Patient died	
24	OS_TIME	Numeric	Time (in days) from enrollment to death, or to last contact if patient is alive	
25	LF_Indicator	Numeric	Censoring flag for local failure. 0=Patient is censored (no local failure); 1=Patient had local failure; 2=Patient had regional failure or distant failure; 3=Patient died	

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Variable Number	Variable Name	Variable Type	Label	Note
26	LF_TIME	Numeric	Time (in days) from enrollment to local failure, or to regional failure, distant failure, death, or to last contact if no relapse or death occurred	
27	RF_Indicator	Numeric	Censoring flag for regional failure. 0=Patient is censored (no regional failure); 1=Patient had regional failure; 2=Patient had distant failure; 3=Patient died	
28	RF_TIME	Numeric	Time (in days) from enrollment to regional failure, or to distant failure, death, or to last contact if no regional/distant failure or death occurred	
29	DF_Indicator	Numeric	Censoring flag for distant failure. 0=Patient is censored (no distant failure); 1=Patient had distant failure; 2=Patient died	
30	DF_TIME	Numeric	Time (in days) from enrollment to distant failure, death, or to last contact if no distant failure or death occurred	
31	rp1Anemia	Character	Did patient experience anemia in weeks 1 - 15?	Pertaining to grade 3 or 4 events.
32	rp2Anemia	Character	Did patient experience anemia in weeks 16 - 30?	
33	rp3Anemia	Character	Did patient experience anemia in weeks 31 - 43?	
34	rp1Diarrhea	Character	Did patient experience diarrhea in weeks 1 - 15?	
35	rp2Diarrhea	Character	Did patient experience diarrhea in weeks 16 - 30?	
36	rp3Diarrhea	Character	Did patient experience diarrhea in weeks 31 - 43?	
37	rp1OralMucositis	Character	Did patient experience mucositis oral in weeks 1 - 15?	
38	rp2OralMucositis	Character	Did patient experience mucositis oral in weeks 16 - 30?	
39	rp3OralMucositis	Character	Did patient experience mucositis oral in weeks 31 - 43?	
40	rp1FebrileNeutropenia	Character	Did patient experience febrile neutropenia in weeks 1 - 15?	
41	rp2FebrileNeutropenia	Character	Did patient experience febrile neutropenia in weeks 16 - 30?	

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Variable Number	Variable Name	Variable Type	Label	Note
42	rp3FebrileNeutropenia	Character	Did patient experience febrile neutropenia in weeks 31 - 43?	
43	rp1Infections	Character	Did patient experience infections and infestations in weeks 1 - 15?	
44	rp2Infections	Character	Did patient experience infections and infestations in weeks 16 - 30?	
45	rp3Infections	Character	Did patient experience infections and infestations in weeks 31 - 43?	
46	rp1Leukopenia	Character	Did patient experience white blood cell decreased in weeks 1 - 15?	
47	rp2Leukopenia	Character	Did patient experience white blood cell decreased in weeks 16 - 30?	
48	rp3Leukopenia	Character	Did patient experience white blood cell decreased in weeks 31 - 43?	
49	rp1Lymphopenia	Character	Did patient experience lymphocyte count decreased in weeks 1 - 15?	
50	rp2Lymphopenia	Character	Did patient experience lymphocyte count decreased in weeks 16 - 30?	
51	rp3Lymphopenia	Character	Did patient experience lymphocyte count decreased in weeks 31 - 43?	
52	rp1Neutropenia	Character	Did patient experience neutrophil count decreased in weeks 1 - 15?	
53	rp2Neutropenia	Character	Did patient experience neutrophil count decreased in weeks 16 - 30?	
54	rp3Neutropenia	Character	Did patient experience neutrophil count decreased in weeks 31 - 43?	
55	rp1Thrombocytopenia	Character	Did patient experience platelet count decreased in weeks 1 - 15?	
56	rp2Thrombocytopenia	Character	Did patient experience platelet count decreased in weeks 16 - 30?	
57	rp3Thrombocytopenia	Character	Did patient experience platelet count decreased in weeks 31 - 43?	
58	rp1Anorexia	Character	Did patient experience anorexia in weeks 1 - 15?	
59	rp2Anorexia	Character	Did patient experience anorexia in weeks 16 - 30?	
60	rp3Anorexia	Character	Did patient experience anorexia in weeks 31 - 43?	
61	rp1Peripheral	Character	Did patient experience peripheral motor neuropathy in weeks 1 - 15?	
62	rp2Peripheral	Character	Did patient experience peripheral motor neuropathy in weeks 16 - 30?	

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Variable Number	Variable Name	Variable Type	Label	Note
63	rp3Peripheral	Character	Did patient experience peripheral motor neuropathy in weeks 31 - 43?	
64	genotype_measured	Character	Was the patient's UGT1A1 genotype measured?	
65	Genotype	Character	If UGT1A1 genotype was measured, the UGT1A1 genotype	
66	wk4to9Neutropenia	Character	For patients on VAC/VI arm with UGT1A1 genotype measured, patient experienced Grade 0-2 or Grade 3-4 neutropenia, with or without fever in weeks 4-9	
67	wk4to9Diarrhea	Character	For patients on VAC/VI arm with UGT1A1 genotype measured, patient experienced Grade 0-2 or Grade 3-4 diarrhea in weeks 4-9	
68	response	Character	Week 13 Response for Group III patients	
69	stratum	Character	The correct stratum according to histology, clinical group, and stage information from centrally reviewed data when available	
70	risk_group1	Character	The variable used in Cox model--Patients are "ARMS only", "ERMS, Stage 2/3, Group III", or "missing"	
71	risk_group2	Character	The variable used in Cox model--Patients are "ARMS only", or "ERMS/NOS"	
72	Death_Before_Prog_Cause	Character	Reason for death for patients who died before disease progression	
73	SMN_types	Character	Type of cancer for SMNs	
74	PmyRopt	Character	Primary reason the patient went off protocol therapy	