

Data Set Name: *acs.sas7bdat*

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Char	7	\$7.	\$8.	Patient ID
2	GENDER	Char	6	\$6.		Gender
3	ITT	Char	3	\$3.		Intent-To-Treat population
4	TREATMENT	Char	13	\$13.		Treatment group
5	AGE_GROUP	Char	5	\$5.		Age group
6	SEVERE	Char	13	\$13.		Severity of ACS
7	HOUR	Char	35	\$35.		Hour - Hospitalization
8	DAYNUM	Num	8	8.		Hospitalization Day
9	RESPRAT	Num	8	8.		Respiratory rate
10	RETRAC	Char	3	\$3.		Breathing-Retractions
11	NASAL	Char	3	\$3.		Breathing-Nasal flaring
12	MUSC	Char	3	\$3.		Breathing-Use of accessory muscles
13	THORAC	Num	8	8.		Thoracic Pain Scale
14	OVERALL	Num	8	8.		Non-thoracic body pain
15	SCALE	Char	20	\$20.		Pain Scale
16	PAIN1	Num	8	1.		Lower Back pain
17	PAIN2	Num	8	1.		Upper Extremities pain
18	PAIN3	Num	8	1.		Head & Neck pain
19	PAIN4	Num	8	1.		Abdomen pain
20	PAIN5	Num	8	1.		Lower Extremities pain
21	SPO2VAL	Num	8	8.		SpO2 current value (%)
22	SUPO2	Char	3	\$3.		Supplemental O2
23	VENTSUP	Char	3	\$3.		Ventilatory Support
24	ACS_COMPSTAT	Char	18	\$18.		When ACS Assessment completed
25	ACS_FUCOMP	Char	3	\$3.		ACS completed at follow-up visits
26	TPOINT	Num	8	8.		Timepoint
27	PHASE	Char	4	\$4.	\$4.	Phase
28	VISIT	Char	15	\$15.		Visit
29	PP	Char	3	\$3.		Per-Protocol population
30	assdays	Num	8			Days between ACS Assessment Date and enrollment
31	TRT_STARTdays	Num	8			Days between Study drug start date and enrollment

Data Set Name: ae.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Char	7	\$7.	\$8.	Patient ID
2	TREATMENT	Char	13	\$13.		Treatment Group
3	ITT	Char	3	\$3.		Intent-To-Treat population
4	AGE_GROUP	Char	5	\$5.		Age group
5	AETEXT	Char	200	\$200.		Adverse Event text
6	SAE	Char	3	\$3.		Serious Adverse Event?
7	OUTCOME	Char	43	\$43.		Outcome
8	RELAT	Char	19	\$19.		Relationship to study drug
9	DEATH	Char	3	\$3.		Subject died?
10	TEAE	Char	3	\$3.		Treatment Emergent AE
11	TRAE	Char	3	\$3.		Treatment Related AE
12	ACTION_NONE	Num	8	1.		Action Taken- None
13	ACTION_CMED	Num	8	1.		Action Taken- Concomitant medication given
14	ACTION_HOSP	Num	8	1.		Action Taken- Hospitalization
15	ACTION_ER	Num	8	1.		Action Taken- ER
16	SEVERE	Char	16	\$16.		Severe AE?
17	SOCN	Char	100	\$100.		AE System Organ Class Name
18	PTERM	Char	100	\$100.		AE Preferred Term
19	ONSETDays	Num	8			Days between AE start date and enrollment
20	TRT_STARTdays	Num	8			Days between Study drug start date and enrollment
21	STOPdays	Num	8			Days between AE stop date and enrollment

Data Set Name: deviation.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Char	7	\$7.	\$8.	Patient ID
2	AGE_GROUP	Char	5	\$5.		Age group
3	ITT	Char	3	\$3.		Intent-To-Treat population
4	DEVITYP	Char	38	\$38.		Type of deviation

Data Set Name: lab.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Char	7	\$7.	\$255.	Patient ID
2	GENDER	Char	6	\$6.		Gender
3	ITT	Char	3	\$3.		Intent-To-Treatpopulation
4	PP	Char	3	\$3.		Per-Protocol population
5	TREATMENT	Char	13	\$13.		Treatment Group
6	AGE_GROUP	Char	5	\$5.		Age Group
7	SEVERE	Char	13	\$13.		Severity of ACS
8	VISIT	Char	6	\$6.	\$6.	Visit
9	PARAM	Char	15	\$15.		Lab Parameter
10	UNITS	Char	7	\$7.		Units
11	VALUEC	Char	8	\$8.		Value
12	VALUEN	Num	8	8.2		Numeric Value
13	VALBASE	Num	8	8.2		Baseline value
14	VALCHG	Num	8	8.2		Change from Baseline
15	PCHG	Num	8	8.2		% Change from Baseline
16	PCHGC	Char	13	\$13.		% Change from Baseline Categories
17	FU_PAIN	Char	3	\$3.		Acute painful episode
18	collDays	Num	8			Days between collection and enrollment
19	TRT_STARTdays	Num	8			Days between Study drug start date and enrollment

Data Set Name: lab_mr.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Char	7	\$7.	\$8.	Patient ID
2	Visit	Char	6	\$6.	\$6.	Visit
3	PARAM	Char	40			BIOMARKER
4	VALUEC	Char	12			BIOMARKER VALUE AS CHARACTER
5	VALUEN	Num	8			BIOMARKER VALUE AS NUMERIC
6	UNITS	Char	4			Biomarker unit
7	VALBASE	Num	8			BIOMARKER BASELINE NUMERIC VALUE
8	VALCHG	Num	8			BIOMARKER CHANGE FROM BASLINE VALUE
9	GENDER	Char	6	\$6.		Gender
10	SEVERE	Char	13	\$13.		Severity of ACS
11	AGE_GROUP	Char	5	\$5.		Age group
12	TREATMENT	Char	13	\$13.		Treatment group
13	ITT	Char	3	\$3.		Intent-To-Treat population
14	PP	Char	3	\$3.		Per-Protocol population
15	TRT_STARTdays	Num	8			Days between Study drug start date and enrollment

Data Set Name: patient.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Char	7	\$7.	\$8.	Patient ID
2	GENDER	Char	6	\$6.		Gender
3	GENOTYPE	Char	3	\$3.		Genotype
4	SEVERE	Char	13	\$13.		Severity of ACS
5	AGE_GROUP	Char	5	\$5.		Age group
6	TREATMENT	Char	13	\$13.		Treatment group
7	CHESTYN	Char	3	\$3.		Chest Radiograph Taken
8	ACS	Num	8	3.		Lifetime episodes of ACS
9	ASTHMA	Char	7	\$7.		Ever diagnosed with asthma
10	ENROLLED	Char	3	\$3.		Enrolled
11	RANDOMIZED	Char	3	\$3.		Randomized
12	ITT	Char	3	\$3.		Intent-To-Treat population
13	RANDNUM	Num	8	8.		Randomization Number
14	DEVI_ANY	Char	3	\$3.		Any major Protocol Deviations ?
15	DISCHARGED	Char	3	\$3.		Discharged from hospital ?
16	DOSED	Char	3	\$3.		Dosed any study drug
17	PP	Char	3	\$3.		Per-Protocol population
18	HRS_ENR_DISCH	Num	8	8.		Number of Hours from enrollment to discharge
19	DAYS_ENR_DISCH	Num	8	8.		Number of days from enrollment to discharge
20	COMPLETED	Char	3	\$3.		Completed study
21	DISCONTINUED	Char	3	\$3.		Did subject discontinued/withdraw early from the study?
22	WTDRW_RES	Char	63	\$63.		Reason for early withdrawal
23	DISC_RES_HYPER	Char	3	\$3.		Discontinued because of hypertension
24	DISC_RES_STROKE	Char	3	\$3.		Discontinued because of stroke
25	DISC_RES_GIHEM	Char	3	\$3.		Discontinued because of GI hemorrhage
26	DISC_RES_PREG	Char	3	\$3.		Discontinued because of pregnancy
27	DISC_RES_INVOP	Char	3	\$3.		Discontinued because of doctor's opinion
28	DA_HYPER	Char	3	\$3.		Any onset Hypertension during hospitalization
29	DA_FLUID	Char	3	\$3.		Any Fluid Overload during hospitalization
30	DA_TRAN	Char	3	\$3.		Any Blood Transfusion during hospitalization
31	DA_SUPO2	Char	3	\$3.		Any Supplemental O2 used during hospitalization
32	DA_FEVER	Char	3	\$3.		Any Fever $\geq 38.5^{\circ}\text{C}$ during hospitalization
33	DA_HYPOX	Char	3	\$3.		Any Hypoxemic during hospitalization
34	FU_PAIN	Char	3	\$3.		Acute painful episode
35	FU_ERVIS	Char	3	\$3.		ER visit
36	FU_HOSP	Char	3	\$3.		Hospitalization

Num	Variable	Type	Len	Format	Informat	Label
37	R_CHEST	Char	3	\$3.		Chest Radiograph taken
38	R_FVC1	Num	8	8.		FVC
39	R_FVC2	Num	8	8.		FVC, predicted
40	R_FEV1	Num	8	8.		FEV
41	R_FEV2	Num	8	8.		FEV, predicted
42	R_FEVFVC1	Num	8	8.		FEV/FVC (%)
43	R_FEVFVC2	Num	8	8.		FEV/FVC (%), predicted
44	R_FEF1	Num	8	8.		FEF (%)
45	R_FEF2	Num	8	8.		FEF (%), predicted
46	R_PEFR1	Num	8	8.		PEFR (L/s)
47	R_PEFR2	Num	8	8.		PEFR (L/s), predicted
48	R_DLCO1	Num	8	8.		DLCO
49	R_DLCO2	Num	8	8.		DLCO, predicted
50	HRS_TRT_DISCH	Num	8	8.1		Hours to discharge after start of study drug
51	DAYS_TRT_DISCH	Num	8	8.		Days to discharge after start of study drug
52	ULN_RR	Num	8	8.		Upper normal limit of respiratory rate
53	HRS_TRT_RES	Num	8	8.1		Hours to symptom resolved after start of study drug
54	ACSDUR	Num	8	8.1		Minimum of duration of ACS symptoms and duration of hospitalization
55	FEVERDUR	Num	8	8.1		Duration of fever
56	SUPODUR	Num	8	8.1		Duration of supplemental O2
57	HYPOXDUR	Num	8	8.1		Duration of Hypoxemia
58	TRANSNUM	Num	8	8.		Number of simple transfusion during hospitalization
59	ACSREBND	Char	3	\$3.		Rebound Hospitalization due to ACS
60	OPIDOSE	Num	8	8.1		Opioid received, non-PCA
61	OPIPCA	Num	8	8.1		Opioid received, PCA
62	OPITOT	Num	8	8.1		Total Opioid received
63	acsspdays	Num	8			Days between ACS Symptoms stop date and enrollment
64	feverspdays	Num	8			Days between Fever stop date and enrollment
65	DISCHDays	Num	8			Days between Date of Discharge and enrollment
66	randdays	Num	8			Days between Randomization Date and enrollment
67	TRT_STARTdays	Num	8			Days between Study drug start date and enrollment
68	supospdays	Num	8			Days between Supplemental O2 stop date and enrollment

Data Set Name: visit.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Char	7	\$7.	\$8.	Patient ID
2	GENDER	Char	6	\$6.		Gender
3	AGE_GROUP	Char	5	\$5.		Age group
4	TREATMENT	Char	13	\$13.		Treatment group
5	ITT	Char	3	\$3.		Intent-To-Treat population
6	PHASE	Char	4	\$4.	\$4.	Phase
7	VISIT	Char	15	\$15.		Visit
8	DAYNUM	Num	8	8.		Hospitalization Day
9	WBC	Num	8	8.1		WBC (x10 ³ /mm ³)
10	RBC	Num	8	8.2		RBC (x10 ⁶ /mm ³)
11	HGB	Num	8	8.1		HGB (g/dL)
12	HCT	Num	8	8.1		HCT (%)
13	MCV	Num	8	8.1		MCV (fL)
14	PLATE	Num	8	8.		Platelets (x10 ³ /mm ³)
15	ABRETIC	Num	8	8.		Abs. Reticulocyte count (x10 ³ /mm ³)
16	RETICPT	Num	8	8.1		% Reticulocyte
17	NOTDO	Num	8	1.		Hematology labs not done
18	PAIN	Char	3	\$3.		Acute Painful Episode
19	HOSP	Char	3	\$3.	\$4.	Hospitalization
20	ERVISIT	Char	3	\$3.		ER Visit
21	WBC_LOW	Num	8	8.1		WBC lower limit (x10 ³ /mm ³)
22	WBC_HIGH	Num	8	8.1		WBC upper limit (x10 ³ /mm ³)
23	RBC_LOW	Num	8	8.2		RBC lower limit (x10 ⁶ /mm ³)
24	RBC_HIGH	Num	8	8.2		RBC upper limit (x10 ⁶ /mm ³)
25	HGB_LOW	Num	8	8.1		HGB lower limit (g/dL)
26	HGB_HIGH	Num	8	8.1		HGB upper limit (g/dL)
27	HCT_LOW	Num	8	8.1		HCT lower limit (%)
28	HCT_HIGH	Num	8	8.1		HCT upper limit (%)
29	MCV_LOW	Num	8	8.1		MCV lower limit (fL)
30	MCV_HIGH	Num	8	8.1		MCV upper limit (fL)
31	PLATE_LOW	Num	8	8.		Platelets lower limit (x10 ³ /mm ³)
32	PLATE_HIGH	Num	8	8.		Platelets upper limit (x10 ³ /mm ³)
33	ABRETIC_LOW	Num	8	8.		Abs. Reticulocyte count lower limit (x10 ³ /mm ³)
34	ABRETIC_HIGH	Num	8	8.		Abs. Reticulocyte count upper limit (x10 ³ /mm ³)
35	RETICPT_LOW	Num	8	8.1		% Reticulocyte lower limit
36	RETICPT_HIGH	Num	8	8.1		% Reticulocyte upper limit

Num	Variable	Type	Len	Format	Informat	Label
37	WBC_CAT	Char	8	\$8.		WBC category
38	RBC_CAT	Char	8	\$8.		RBC category
39	HGB_CAT	Char	8	\$8.		HGB category
40	HCT_CAT	Char	8	\$8.		HCT category
41	MCV_CAT	Char	8	\$8.		MCV category
42	PLATE_CAT	Char	8	\$8.		Platelets category
43	ABRETIC_CAT	Char	8	\$8.		Abs. Reticulocyte count category
44	RETICPT_CAT	Char	8	\$8.		% Reticulocyte category
45	BASEWBC_CAT	Char	8	\$8.		WBC category-Baseline
46	BASERBC_CAT	Char	8	\$8.		RBC category-Baseline
47	BASEHGB_CAT	Char	8	\$8.		HGB category-Baseline
48	BASEHCT_CAT	Char	8	\$8.		HCT category-Baseline
49	BASEMCV_CAT	Char	8	\$8.		MCV category-Baseline
50	BASEPLATE_CAT	Char	8	\$8.		Platelets category-Baseline
51	BASEABRETIC_CAT	Char	8	\$8.		Abs. Reticulocyte count category-Baseline
52	BASERETICPT_CAT	Char	8	\$8.		% Reticulocyte category-Baseline
53	WRSTWBC_CAT	Char	8	\$8.		WBC category- Worst among post-baselines
54	WRSTRBC_CAT	Char	8	\$8.		RBC category- Worst among post-baselines
55	WRSTHGB_CAT	Char	8	\$8.		HGB category- Worst among post-baselines
56	WRSTHCT_CAT	Char	8	\$8.		HCT category-Worst among post-baselines
57	WRSTMCV_CAT	Char	8	\$8.		MCV category-Worst among post-baselines
58	WRSTPLATE_CAT	Char	8	\$8.		Platelets category-Worst among post-baselines
59	WRSTABRETIC_CAT	Char	8	\$8.		Abs. Reticulocyte count category-Worst among post-baselines
60	WRSTRETICPT_CAT	Char	8	\$8.		% Reticulocyte category-Worst among post-baselines
61	BASEWBC	Num	8	8.1		Baseline WBC
62	BASERBC	Num	8	8.2		Baseline RBC (x10 ⁶ /mm ³)
63	BASEHGB	Num	8	8.1		Baseline HGB (g/dL)
64	BASEHCT	Num	8	8.1		Baseline HCT (%)
65	BASEMCV	Num	8	8.1		Baseline MCV (fL)
66	BASEPLATE	Num	8	8.		Baseline Platelets (x10 ³ /mm ³)
67	BASERETICPT	Num	8	8.1		Baseline % Reticulocyte
68	CHANGEBASEWBC	Num	8	8.1		Change from Baseline WBC
69	CHANGEBASERBC	Num	8	8.2		Change from Baseline RBC (x10 ⁶ /mm ³)
70	CHANGEBASEHGB	Num	8	8.1		Change from Baseline HGB (g/dL)
71	CHANGEBASEHCT	Num	8	8.1		Change from Baseline HCT (%)
72	CHANGEBASEMCV	Num	8	8.1		Change from Baseline MCV (fL)
73	CHANGEBASEPLATE	Num	8	8.		Change from Baseline Platelets (x10 ³ /mm ³)
74	CHANGEBASERETICPT	Num	8	8.1		Change from Baseline % Reticulocyte
75	PP	Char	3	\$3.		Per-Protocol population

Num	Variable	Type	Len	Format	Informat	Label
76	TMPT	Char	5	\$5.		Timepoint during Hospitalization
77	COLLdays	Num	8			Days between Hematology labs collection date and enrollment

Data Set Name: vital.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Char	7	\$7.	\$8.	Patient ID
2	GENDER	Char	6	\$6.		Gender
3	AGE_GROUP	Char	5	\$5.		Age group
4	TREATMENT	Char	13	\$13.		Treatment group
5	ITT	Char	3	\$3.		Intent-To-Treat population
6	PHASE	Char	4	\$4.	\$4.	Phase
7	VISIT	Char	15	\$15.		Visit
8	DAYNUM	Num	8	8.		Hospitalization Day
9	SEQNO	Char	3	\$3.	\$3.	SEQNO
10	VTL_COMPLETE	Char	3	\$3.		Follow-up assessment completed
11	TEMP	Num	8	8.1		Temperature (°C)
12	HR	Num	8	8.		Heart Rate (BPM)
13	RR	Num	8	8.		Respiration Rate (RR)
14	SYS1	Num	8	8.		Maximum Systolic (mmHg)
15	DIA2	Num	8	8.		Maximum Diastolic (mmHg)
16	O2SAT	Num	8	8.		Minimum O2 Saturation (%)
17	HYPER	Char	3	\$3.		Onset Hypertension
18	HYPER_REASON	Char	20	\$20.		Reason for Onset Hypertension
19	HYPER_TREAT	Char	3	\$3.		Hypertension, Treatment Required
20	FLUID	Char	3	\$3.		Fluid Overload
21	TRAN	Char	3	\$3.		Blood Transfusion
22	TRANTYP	Char	8	\$8.		Transfusion Type
23	NUMSIMP	Num	8	8.		Number of simple transfusions
24	SUPO2_YN	Char	3	\$3.		Using supplemental O2?
25	FEVER	Char	3	\$3.		Fever >= 38.5 °C
26	HYPOX	Char	3	\$3.		Hypoxemic
27	PP	Char	3	\$3.		Per-Protocol population
28	ASSDays	Num	8			Days between Assessment Date and enrollment

Data Set Name: *x_ray.sas7bdat*

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Char	7	\$7.	\$8.	Patient ID
2	GENDER	Char	6	\$6.		Gender
3	ITT	Char	3	\$3.		Intent-To-Treat population
4	TREATMENT	Char	13	\$13.		Treatment group
5	PULYN	Char	3	\$3.		Pulmonary Infiltrate?
6	NEWYN	Char	8	\$8.		New Pulmonary Infiltrate?
7	COMM	Char	200	\$200.		Comment
8	TMPT	Char	15	\$15.		Timepoint
9	PP	Char	3	\$3.		Per-Protocol population
10	TRT_STARTDays	Num	8			Days between Study drug start date and enrollment
11	DISCHDays	Num	8			Days between Date of discharge and enrollment
12	xrayDays	Num	8			Days between Date of X-Ray and enrollment