Data Set Name: outcomes.sas7bdat

Num	Variable	Type	Len	Format	Label
1	ID	Num	8		Random ID
2	drug	Num	8	DRUG2F.	Trt Grp: 1=Spironolactone, 2=Placebo
3	death	Num	8		1=Any Cause death (T079)
4	cvd_death	Num	8		1=CVD Death (T079)
5	time_death	Num	8		Time to death (T079) or Censor (T030)
6	anyhosp	Num	8		1=Any Hospitalization (T027)
7	time_anyhosp	Num	8		Time to first Hospitalization (T027) or Censor (T030)
8	hfhosp	Num	8		1=Hosp for Heart Failure (T070)
9	time_hfhosp	Num	8		Time to first Hosp for Heart Failure (T070) or Censor (T030)
10	abortedca	Num	8		1=Aborted Cardiac Arrest (T076)
11	time_abortedca	Num	8		Time to Aborted Cardiac Arrest (T076) or Censor (T030)
12	mi	Num	8		1=Adjudicated Myocardial Infarction (T030)
13	time_mi	Num	8		Time to first MI (T072) or Censor (T030)
14	stroke	Num	8		1=Adjudicated Stroke (T074)
15	time_stroke	Num	8		Time to first stroke (T074) or Censor (T030)
16	primary_ep	Num	8		1=Primary Endpoint (calculated)
17	time_primary_ep	Num	8		Time to Primary Endpoint or Censor (calculated)

Data Set Name: canrenon_as.sas7bdat

Num	Variable	Type	Len	Label
1	ID	Num	8	ID
2	Canrenone	Num	8	Canrenone concentration (ng/ml)

Data Set Name: echo_baseline.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	visit1	Char	8			Baseline visit when Echo occurred
3	occurred_on1	Num	8			Time from randomization to date when echo occurred (years)
4	ecc_mr	Num	8	BEST12.	BEST32.	Eccentric mitral regurgitation
5	mr_mod	Num	8	BEST12.	BEST32.	Moderate or greater mitral regurgitation
6	lvs	Num	8	BEST12.	BEST32.	Interventricular septum thickness
7	lvpw	Num	8	BEST12.	BEST32.	Posterior wall thickness
8	lvdd	Num	8	BEST12.	BEST32.	End-diastolic left ventricular diameter
9	ap4vd	Num	8	BEST12.	BEST32.	4 - Chamber end diastolic volume
10	ap4vs	Num	8	BEST12.	BEST32.	4 - Chamber end systolic volume
11	ap4lavd	Num	8	BEST12.	BEST32.	4 - Chamber, left atrial volume
12	ap2vd	Num	8	BEST12.	BEST32.	2 - Chamber, end diastolic volume
13	ap2vs	Num	8	BEST12.	BEST32.	2 - Chamber, end systolic volume
14	lawidth	Num	8	BEST12.	BEST32.	Maximal left atrial anterior-posterior diameter
15	ewave	Num	8	BEST12.	BEST32.	Peak E wave velocity
16	awave	Num	8	BEST12.	BEST32.	Peak A wave velocity
17	ealateral	Num	8	BEST12.	BEST32.	Lateral early diastolic myocardial velocity
18	aalateral	Num	8	BEST12.	BEST32.	Lateral late diastolic myocardial velocity
19	mrjet	Num	8	BEST12.	BEST32.	Mitral regurgitation jet area
20	dt	Num	8	BEST12.	BEST32.	E wave deceleration time
21	tr	Num	8	BEST12.	BEST32.	Peak tricuspid regurgitation velocity
22	ef_4ch	Num	8	BEST12.	BEST32.	4 - chamber, Ejection Fraction
23	ef_2ch	Num	8	BEST12.	BEST32.	2 - chamber, Ejection Fraction
24	earatio	Num	8	BEST12.	BEST32.	E/A ratio
25	la2edv	Num	8	BEST12.	BEST32.	2 - Chamber, left atrial volume
26	lvesd	Num	8	BEST12.	BEST32.	End-systolic left ventricular diameter
27	easept	Num	8	BEST12.	BEST32.	Septal early diastolic myocardial velocity
28	aasept	Num	8	BEST12.	BEST32.	Septal late diastolic myocardial velocity
29	rveda	Num	8	BEST12.	BEST32.	RV end diastolic area
30	rvesa	Num	8	BEST12.	BEST32.	RV end systolic area
31	salat	Num	8	BEST12.	BEST32.	Lateral systolic myocardial velocity
32	sasept	Num	8	BEST12.	BEST32.	Septal systolic myocardial velocity
33	laa	Num	8	BEST12.	BEST32.	Left atrial area
34	lvwtmean	Num	8	BEST12.	BEST32.	Mean LV wall thickness
35	lvmass	Num	8	BEST12.	BEST32.	LV Mass
36	ef_tot	Num	8	BEST12.	BEST32.	Ejection Fraction

Num	Variable	Type	Len	Format	Informat	Label
37	eeprime_sept	Num	8	BEST12.	BEST32.	E/Em septal ratio
38	rvfac	Num	8	BEST12.	BEST32.	RV fractional area change
39	eeprime_lat	Num	8	BEST12.	BEST32.	E/Em lateral ratio
40	lvef	Num	8	BEST12.	BEST32.	Simpson Ejection fraction
41	lvedv_t	Num	8	BEST12.	BEST32.	Teicholtz end-diastolic volume
42	lvesv_t	Num	8	BEST12.	BEST32.	Teicholtz end-systolic volume
43	lvef_t	Num	8	BEST12.	BEST32.	Teicholtz Ejection fraction
44	lvedv	Num	8	BEST12.	BEST32.	End-diastolic volume
45	lvesv	Num	8	BEST12.	BEST32.	End-systolic volume
46	lav	Num	8	BEST12.	BEST32.	LA volume
47	rwt	Num	8	BEST12.	BEST32.	LV relative wall thickness
48	mrja_laa	Num	8	BEST12.	BEST32.	MR jet area-to-left atrial area ratio
49	sv	Num	8	BEST12.	BEST32.	Stroke Volume
50	eprime_abnl	Num	8	BEST12.	BEST32.	Abnormal E' (septal or lateral)
51	ddfxn_grade	Num	8	BEST12.	BEST32.	Diastolic dysfunction grade
52	ddfxn_red	Num	8	BEST12.	BEST32.	Diastolic dysfunction grade (modified Olmsted criteria)
53	gls	Num	8	BEST12.	BEST32.	Longitudinal Strain
54	gls_abnl	Num	8	BEST12.	BEST32.	Abnormal Longitudinal Strain
55	gls_q	Num	8	BEST12.	BEST32.	Quartile of Longitudinal Strain
56	as_mod	Num	8	BEST12.	BEST32.	Moderate or greater aortic stenosis
57	ai_mod	Num	8	BEST12.	BEST32.	Moderate aortic regurgitation
58	prosthetic_valve	Num	8	BEST12.	BEST32.	Presense of prosethetic valve
59	no_colordoppler	Num	8	BEST12.	BEST32.	Was color Doppler missing in study (1=Yes, 2=No)
60	avpeak	Num	8	BEST12.	BEST32.	AV peak velocity
61	rvotvti	Num	8	BEST12.	BEST32.	Right ventricular outflow tract velocity time integral
62	rwt_abnl	Num	8	BEST12.	BEST32.	Abnormal relative wall thickness
63	pvr	Num	8	BEST12.	BEST32.	Pulmonary vasular resistance
64	valve_dz	Num	8	BEST12.	BEST32.	Significant valvular disease

Data Set Name: echo_followup.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	visit1	Char	9			Follow up visit when Echo occurred
3	occurred_on1	Num	8			Time from randomization to date when echo occurred (years)
4	ecc_mr	Num	8	BEST12.	BEST32.	Eccentric mitral regurgitation
5	mr_mod	Num	8	BEST12.	BEST32.	Moderate or greater mitral regurgitation
6	lvs	Num	8	BEST12.	BEST32.	Interventricular septum thickness
7	lvpw	Num	8	BEST12.	BEST32.	Posterior wall thickness
8	lvdd	Num	8	BEST12.	BEST32.	End-diastolic left ventricular diameter
9	ap4vd	Num	8	BEST12.	BEST32.	4 - Chamber end diastolic volume
10	ap4vs	Num	8	BEST12.	BEST32.	4 - Chamber end systolic volume
11	ap4lavd	Num	8	BEST12.	BEST32.	4 - Chamber, left atrial volume
12	ap2vd	Num	8	BEST12.	BEST32.	2 - Chamber, end diastolic volume
13	ap2vs	Num	8	BEST12.	BEST32.	2 - Chamber, end systolic volume
14	lawidth	Num	8	BEST12.	BEST32.	Maximal left atrial anterior-posterior diameter
15	ewave	Num	8	BEST12.	BEST32.	Peak E wave velocity
16	awave	Num	8	BEST12.	BEST32.	Peak A wave velocity
17	ealateral	Num	8	BEST12.	BEST32.	Lateral early diastolic myocardial velocity
18	aalateral	Num	8	BEST12.	BEST32.	Lateral late diastolic myocardial velocity
19	mrjet	Num	8	BEST12.	BEST32.	Mitral regurgitation jet area
20	dt	Num	8	BEST12.	BEST32.	E wave deceleration time
21	tr	Num	8	BEST12.	BEST32.	Peak tricuspid regurgitation velocity
22	ef_4ch	Num	8	BEST12.	BEST32.	4 - chamber, Ejection Fraction
23	ef_2ch	Num	8	BEST12.	BEST32.	2 - chamber, Ejection Fraction
24	earatio	Num	8	BEST12.	BEST32.	E/A ratio
25	la2edv	Num	8	BEST12.	BEST32.	2 - Chamber, left atrial volume
26	lvesd	Num	8	BEST12.	BEST32.	End-systolic left ventricular diameter
27	easept	Num	8	BEST12.	BEST32.	Septal early diastolic myocardial velocity
28	aasept	Num	8	BEST12.	BEST32.	Septal late diastolic myocardial velocity
29	rveda	Num	8	BEST12.	BEST32.	RV end diastolic area
30	rvesa	Num	8	BEST12.	BEST32.	RV end systolic area
31	salat	Num	8	BEST12.	BEST32.	Lateral systolic myocardial velocity
32	sasept	Num	8	BEST12.	BEST32.	Septal systolic myocardial velocity
33	laa	Num	8	BEST12.	BEST32.	Left atrial area
34	lvwtmean	Num	8	BEST12.	BEST32.	Mean LV wall thickness
35	lvmass	Num	8	BEST12.	BEST32.	LV Mass
36	ef_tot	Num	8	BEST12.	BEST32.	Ejection Fraction

Num	Variable	Type	Len	Format	Informat	Label
37	eeprime_sept	Num	8	BEST12.	BEST32.	E/Em septal ratio
38	rvfac	Num	8	BEST12.	BEST32.	RV fractional area change
39	eeprime_lat	Num	8	BEST12.	BEST32.	E/Em lateral ratio
40	lvef	Num	8	BEST12.	BEST32.	Simpson Ejection fraction
41	lvedv_t	Num	8	BEST12.	BEST32.	Teicholtz end-diastolic volume
42	lvesv_t	Num	8	BEST12.	BEST32.	Teicholtz end-systolic volume
43	lvef_t	Num	8	BEST12.	BEST32.	Teicholtz Ejection fraction
44	lvedv	Num	8	BEST12.	BEST32.	End-diastolic volume
45	lvesv	Num	8	BEST12.	BEST32.	End-systolic volume
46	lav	Num	8	BEST12.	BEST32.	LA volume
47	rwt	Num	8	BEST12.	BEST32.	LV relative wall thickness
48	mrja_laa	Num	8	BEST12.	BEST32.	MR jet area-to-left atrial area ratio
49	sv	Num	8	BEST12.	BEST32.	Stroke Volume
50	eprime_abnl	Num	8	BEST12.	BEST32.	Abnormal E' (septal or lateral)
51	ddfxn_grade	Num	8	BEST12.	BEST32.	Diastolic dysfunction grade
52	ddfxn_red	Num	8	BEST12.	BEST32.	Diastolic dysfunction grade (modified Olmsted criteria)

Data Set Name: q001.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	VISIT	Char	4	$4.	$4.	Q001: A3. Visit
3	qol_dt1	Num	8			Time between randomization and date QOL instruments completed
4	QOL_TYPE	Num	8	X1149F.	3.	Q001: A5. How were the questionnaires completed
5	QOL_COMP	Num	8	X1189F.	3.	Q001: A6. Who completed the quality of life questionnaires
6	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification

Data Set Name: q002.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	VISIT	Char	4	$4.	$4.	Q002: A3. Visit
3	DRESS	Num	8	X1133F.	3.	Q002: B1a. Dressing yourself
4	SHOWER	Num	8	X1133F.	3.	Q002: B1b. Showering/Bathing
5	WALK	Num	8	X1133F.	3.	Q002: B1c. Walking 1 block on level ground
6	YARDWORK	Num	8	X1133F.	3.	Q002: B1d. Doing yardwork
7	CLIMB	Num	8	X1133F.	3.	Q002: B1e. Climbing a flight of stairs
8	HURRY	Num	8	X1133F.	3.	Q002: B1f. Hurrying or jogging
9	SYMP_CHANGE	Num	8	X1160F.	3.	Q002: B2. Have symptoms of heart failure changed
10	SWELL_NUM	Num	8	X1130F.	3.	Q002: B3. How many times do you have swelling in your feet
11	SWELL_FEEL	Num	8	X1136F.	3.	Q002: B4. How much has swelling in your feet bothered you
12	FATIGUE_NUM	Num	8	X1101F.	3.	Q002: B5. How many time has fatigue limited ability
13	FATIGUE_FEEL	Num	8	X1134F.	3.	Q002: B6. How much has fatigue bothered you
14	BREATH_NUM	Num	8	X1101F.	3.	Q002: B7. How many times has shortness of breath limited
15	BREATH_FEEL	Num	8	X1135F.	3.	Q002: B8. How much has your shortness of breath bothered you
16	BREATH_SLEEP	Num	8	X1131F.	3.	Q002: B9. Forced to sleep sitting up due to shortness of breath
17	TO_DO	Num	8	X1168F.	3.	Q002: B10. If heart failure gets worse
18	UNDERSTAND	Num	8	X1126F.	3.	Q002: B11. Keep heart failure from getting worse
19	LIMIT_LIFE	Num	8	X1154F.	3.	Q002: B12. How much has heart failure limited enjoyment of life
20	REST_LIFE	Num	8	X1167F.	3.	Q002: B13. Heart failure right now, how would you feel
21	DISCOURAGED	Num	8	X1148F.	3.	Q002: B14. How often have you felt discouraged because of heart failure
22	HOBBIES	Num	8	X1177F.	3.	Q002: B15a. Hobbies, recreational activities
23	WORKING	Num	8	X1177F.	3.	Q002: B15b. Working or doing household chores
24	VISITING	Num	8	X1177F.	3.	Q002: B15c. Visiting family or friends out of your home
25	INTIMATE	Num	8	X1177F.	3.	Q002: B15d. Intimate relationships with loved ones
26	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification
27	physcnt	Num	8			KCCQ: Physical Limitation count
28	phys_limit_score	Num	8			KCCQ: Physical Limitation score
29	symp_stab_score	Num	8			KCCQ: Symptom Stability score
30	sympcnt	Num	8			KCCQ: Symptom Frequency count
31	s3	Num	8			KCCQ: Symptom Frequency count (swell_num)
32	s5	Num	8			KCCQ: Symptom Frequency count (fatigue_num)
33	s7	Num	8			KCCQ: Symptom Frequency count (breath_num)
34	s9	Num	8			KCCQ: Symptom Frequency count (breath_sleep)
35	symp_freq_score	Num	8			KCCQ: Symptom Frequency score
36	symburcnt	Num	8			KCCQ: Symptom Burden count

Num	Variable	Type	Len	Format	Informat	Label
37	symp_bur_score	Num	8			KCCQ: Symptom Burden score
38	tot_symp_score	Num	8			KCCQ: Total Symptom score
39	seffcnt	Num	8			KCCQ: Self-Efficacy count
40	self_eff_score	Num	8			KCCQ: Self-Efficacy score
41	qolcnt	Num	8			KCCQ: Quality of Life count
42	qol_score	Num	8			KCCQ: Quality of Life score
43	soclimcnt	Num	8			KCCQ: Social Limitation count
44	soc_limit_score	Num	8			KCCQ: Social Limitation score
45	overall_sum_score	Num	8			KCCQ: Overall Summary score
46	clin_sum_score	Num	8			KCCQ: Clinical Summary score

Data Set Name: q003.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	VISIT	Char	4	$4.	$4.	Q003: A3. Visit
3	HEALTH_SCALE	Num	8	X1072F.	4.	Q003: B1. Visual Analog Scale
4	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification

Data Set Name: q004.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	VISIT	Char	4	$4.	$4.	Q004: A3. Visit
3	PLEASURE	Num	8	X1083F.	3.	Q004: B1. Little interest or pleasure in doing things
4	FEEL_DOWN	Num	8	X1083F.	3.	Q004: B2. Feeling down, depressed, or hopeless
5	SLEEPING	Num	8	X1083F.	3.	Q004: B3. Trouble falling or staying asleep or sleeping too much
6	FEEL_TIRED	Num	8	X1083F.	3.	Q004: B4. Feeling tired or having little energy
7	EATING	Num	8	X1083F.	3.	Q004: B5. Poor appetite or overeating
8	FEEL_BAD	Num	8	X1083F.	3.	Q004: B6. Feeling bad about yourself - or that you are a failure
9	CONCENTRATE	Num	8	X1083F.	3.	Q004: B7. Trouble concentrating on things
10	MOVING	Num	8	X1083F.	3.	Q004: B8. Moving or speaking so slowly
11	HURT_SELF	Num	8	X1083F.	3.	Q004: B9. Thoughts that you would be better off dead
12	DIFFICULT	Num	8	X1084F.	3.	Q004: B10. How difficult have these problems made it for you to do work
13	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification
14	phqcat	Num	8	PHQFMT.		PHQ score category
15	depressed	Num	8	NYF.		Depression Yes/No variable based on total PHQ score

Data Set Name: q005.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	VISIT	Char	4	$4.	$4.	Q005: A3. Visit
3	O_CHANGE	Num	8	X1108F.	3.	Q005: B1. Overall Treatment Evaluation - CHF
4	BETTER	Num	8	X1102F.	3.	Q005: B2. Better
5	WORSE	Num	8	X1103F.	3.	Q005: B3. Worse
6	IMPORTANT	Num	8	X1169F.	3.	Q005: B4. Overall Treatment Effect
7	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification
8	score	Num	8			McMaster OTE: Total score

Data Set Name: t001.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	VISIT	Char	4	$4.	$4.	T001: A3. Visit
3	ICF	Num	8	X2615F.	3.	T001: B1. Has the subject signed a consent form
4	icf_dt1	Num	8			Time between Randomization and Consent Signed (years)
5	ECHO	Num	8	X2615F.	3.	T001: B1b. Has the subject consented to sending the TTE for QC?
6	ICF_REP	Num	8	X2615F.	3.	T001: C1. Has the subject signed a consent form for sub-study?
7	icf_rep_dt1	Num	8			Time between Randomization and Sub Study Consent Signed (years)
8	ICF_BLOOD	Num	8	X2615F.	3.	T001: C2. Has subject consented to blood specimen analysis
9	ICF_BLOODURI	Num	8	X2615F.	3.	T001: C2. Has subject consented to blood and urine specimen analysis?
10	ICF_URINE	Num	8	X2615F.	3.	T001: C3. Has subject consented to urine specimen analysis
11	ICF_DNA	Num	8	X2615F.	3.	T001: C3. Has subject consented to DNA specimen analysis?
12	DNA_DISEASES	Num	8	X2634F.	3.	T001: C3a. Diseases to be studied
13	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification

Data Set Name: t002.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	VISIT	Char	4	$4.	$4.	T002: A3. Visit
3	IN_AGE	Num	8	X2730F.	3.	T002: B1. Male or female age 50 years or older
4	IN_HF	Num	8	X2730F.	3.	T002: B2. Heart failure
5	IN_LVEF	Num	8	X2730F.	3.	T002: B3. Left ventricular ejection fraction
6	IN_SBP	Num	8	X2730F.	3.	T002: B4. Controlled systolic BP
7	IN_K	Num	8	X2730F.	3.	T002: B5. Serum potassium
8	IN_HOSP	Num	8	X2730F.	3.	T002: B6a. At least one hospital admission
9	IN_BNP	Num	8	X2730F.	3.	T002: B6b. Brain natriuretic peptide
10	IN_PREG	Num	8	X2731F.	3.	T002: B7. Contraception
11	IN_COMPLY	Num	8	X2730F.	3.	T002: B8. Willing to comply with visits
12	IN_ICF	Num	8	X2730F.	3.	T002: B9. Informed consent
13	EX_ILL	Num	8	X2730F.	3.	T002: C1. Severe systemic illness
14	EX_COPD	Num	8	X2730F.	3.	T002: C2. Chronic pulmonary disease
15	EX_HOCM	Num	8	X2730F.	3.	T002: C3. Known obstructive cardiomyopathy
16	EX_VHD	Num	8	X2730F.	3.	T002: C4. Primary hemodynamically
17	EX_AFIB	Num	8	X2730F.	3.	T002: C5. Atrial fibrillation
18	EX_MI	Num	8	X2730F.	3.	T002: C6. Myocardial infarction
19	EX_CABG	Num	8	X2730F.	3.	T002: C7. Coronary artery bypass graft surgery
20	EX_PCI	Num	8	X2730F.	3.	T002: C8. Percutaneous coronary intervention
21	EX_HRTTRANS	Num	8	X2730F.	3.	T002: C9. Heart transplant recipient
22	EX_LVAD	Num	8	X2730F.	3.	T002: C10. Currently implanted device
23	EX_STROKE	Num	8	X2730F.	3.	T002: C11. Stroke in past 90 days
24	EX_SBP	Num	8	X2730F.	3.	T002: C12. Systolic blood pressure (SBP) > 160 mm Hg
25	EX_HYPO	Num	8	X2730F.	3.	T002: C13. Known orthostatic hypotension
26	EX_GI	Num	8	X2730F.	3.	T002: C14. Gastrointestinal disorder
27	EX_ALDO	Num	8	X2730F.	3.	T002: C15. Use of any aldosterone antagonist or potassium sparing medication in last 7 days
28	EX_ALDO_14	Num	8	X2730F.	3.	T002: C15. Use of any aldosterone antagonist or potassium sparing medication in last 14 days
29	EX_INTOL	Num	8	X2730F.	3.	T002: C16. Intolerance to aldosterone antagonists
30	EX_LITH	Num	8	X2730F.	3.	T002: C17. Current lithium use
31	EX_TRIAL	Num	8	X2730F.	3.	T002: C18. Current participation in other trial
32	EX_PI	Num	8	X2730F.	3.	T002: C19. Condition that may prevent subject from adhering to protocol
33	EX_HYPERK	Num	8	X2730F.	3.	T002: C20. History of hyperkalemia
34	EX_RENAL	Num	8	X2730F.	3.	T002: C21. Severe renal dysfunction
35	EX_HEPATIC	Num	8	X2730F.	3.	T002: C22. Known chronic hepatic disease

Num	Variable	Type	Len	Format	Informat	Label
36	IN_ALL	Num	8	X2730F.	3.	T002: D1. Are all inclusion criteria questions answered YES
37	EX_ALL	Num	8	X2730F.	3.	T002: D2. Are all exclusion criteria questions answered NO
38	elig_dt_1	Num	8			Time between randomization and eligibility date (years)
39	STATUS	Num	8	X2683F.	3.	T002: D4. Subject status on this date
40	PRIOR_SPIRO	Num	8	X2730F.	3.	T002: D5. Has subject used aldosterone antagonist in 30 days prior?
41	BNP_YN	Num	8	X2730F.	3.	T002: E1. Brain natriuretic peptide (BNP) or N-terminal pro-BNP 30 days prior to eligibility
42	BNP_TYPE	Num	8	X2639F.	3.	T002: E2. BNP Type
43	BNP_VAL	Num	8	X2602F.	6.	T002: E2a. Result in pg/ml
44	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification

Data Set Name: t002_mdatrs.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	prior_dt1	Num	8			Time between Randomization and Date last used
3	PRIOR_MED	Char	50	$50.	$50.	T002: D5a. Aldosterone Antagonist / Potassium Sparing Medication

Data Set Name: t003.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Random ID
2	VISIT	Char	4	$4.	$4.	T003: A3. Visit
3	age_entry	Num	8			Age Entering Study
4	GENDER	Num	8	GENDFMT.	3.	Gender
5	RACE_WHITE	Num	8	X2621F.	3.	T003: B3a. White or Caucasian
6	RACE_BLACK	Num	8	NYF.	3.	Race: Black
7	RACE_ASIAN	Num	8	X2621F.	3.	T003: B3c. Asian
8	RACE_OTHER	Num	8	X2621F.	3.	T003: B3f. Race: Other
9	race_cat	Num	8	RACE_CATFMT.		3-Category Race Variable (Black/White/All Others)
10	ETHNICITY	Num	8	X2615F.	3.	T003: B4. Is subject of Hispanic, Latino, or Spanish origin?
11	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification

Data Set Name: t004.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Random ID
2	VISIT	Char	4	$4.	$4.	T004: A3. Visit
3	visit_dt1	Num	8			Time from Randomization to visit date (years)
4	DYSP_CUR	Num	8	YNU2FMT.	3.	T004: C1a. Dyspnea: Present at screening?
5	DYSP_YR	Num	8	YNU2FMT.	3.	T004: C1b. Dyspnea: experienced in past year?
6	ORT_CUR	Num	8	YNU2FMT.	3.	T004: C2a. Orthopnea: Present at screening?
7	ORT_YR	Num	8	YNU2FMT.	3.	T004: C2b. Orthopnea: experienced in past year?
8	DOE_CUR	Num	8	YNU2FMT.	3.	T004: C3a. Dyspnea on exertion: Present at screening?
9	DOE_YR	Num	8	YNU2FMT.	3.	T004: C3b. Dyspnea on exertion: experienced in past year?
10	RALES_CUR	Num	8	YNU2FMT.	3.	T004: D1a. Rales present at screening?
11	RALES_YR	Num	8	YNU2FMT.	3.	T004: D1b. Rales: experienced in past year?
12	JVP_CUR	Num	8	YNU2FMT.	3.	T004: D2a. JVP: Present at screening?
13	JVP_YR	Num	8	YNU2FMT.	3.	T004: D2b. JVP: experienced in past year?
14	EDEMA_CUR	Num	8	YNU2FMT.	3.	T004: D3a. Edema: Present at screening?
15	EDEMA_YR	Num	8	YNU2FMT.	3.	T004: D3b. Edema: experienced in past year?
16	XRAY_CUR	Num	8	YNU2FMT.	3.	T004: D4a. XRay: Present at screening?
17	XRAY_YR	Num	8	YNU2FMT.	3.	T004: D4b. XRay: experienced in past year?
18	EF	Num	8	X2602F.	3.	T004: E1. Ejection Fraction
19	ef_dt3	Num	8			Time from Randomization to Ejecttion fraction Assessment date (years)
20	EF_SOURCE	Num	8	X2658F.	3.	T004: E3. Source
21	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification

Data Set Name: t005.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	VISIT	Char	4	$4.	$4.	T005: A3. Visit
3	visit_dt1	Num	8			Time between randomization and visit date (years)
4	CHF_HOSP	Num	8	X2615F.	3.	T005: B2. Previous hospitalization for CHF
5	chfdc_dt3	Num	8			Time Between randomization and Hospitilization for Cardiac Heart Failure (years)
6	MI	Num	8	X2615F.	3.	T005: B3. Previous myocardial infarction
7	mi_dt3	Num	8			Time Between randomization and Myocardial Infarction (years)
8	STROKE	Num	8	X2615F.	3.	T005: B4. Stroke
9	stroke_dt3	Num	8			Time Between randomization and stroke (years)
10	CABG	Num	8	X2615F.	3.	T005: B5. Coronary artery bypass graft surgery
11	cabg_dt3	Num	8			Time Between randomization and Coronary Artery Bypass Graft surgery (years)
12	PCI	Num	8	X2615F.	3.	T005: B6. Percutaneous Coronary Revascularization
13	pci_dt3	Num	8			Time Between randomization and Percutaneous Coronary Revascularization (years)
14	ANGINA	Num	8	X2730F.	3.	T005: B7. Angina Pectoris
15	COPD	Num	8	X2730F.	3.	T005: B8. Chronic Obstructive Pulmonary Disease
16	ASTHMA	Num	8	X2730F.	3.	T005: B9. Asthma
17	HTN	Num	8	X2730F.	3.	T005: B10. Hypertension
18	PAD	Num	8	X2730F.	3.	T005: B11. Peripheral Arterial Disease
19	DYSLIPID	Num	8	X2730F.	3.	T005: B12. Dyslipidemia
20	ICD	Num	8	X2730F.	3.	T005: B13. Implanted cardioverter defibrillator
21	PACEMAKER	Num	8	X2730F.	3.	T005: B14. Pacemaker implanted
22	AFIB	Num	8	X2730F.	3.	T005: B15. Atrial fibrillation
23	AFIB_PAROX	Num	8	X2730F.	3.	T005: B15a. Atrial fibrillation: Paroxysmal atrial fibrillation
24	AFIB_CHRON	Num	8	X2730F.	3.	T005: B15b. Atrial fibrillation: Chronic atrial fibrillation
25	THYROID	Num	8	X2730F.	3.	T005: B16. Thyroid disease
26	THYR_HPR	Num	8	X2730F.	3.	T005: B16a. Thyroid disease: Hyperthyroidism
27	THYR_HYPO	Num	8	X2730F.	3.	T005: B16b. Thyroid disease: Hypothyroidism
28	DM	Num	8	X2730F.	3.	T005: B17. Diabetes Mellitus
29	DM_AGE_YR	Num	8	X2602F.	3.	T005: B17a. Age of DM onset (years)
30	DM_DUR_YR	Num	8	X2602F.	3.	T005: B17b. Duration since DM diagnosis (years)
31	INSULIN	Num	8	X2620F.	3.	T005: B17c1. Treatment for diabetes mellitus: Insulin
32	dm_cat	Num	8	DM_CATFMT.		3-Category Diabetes Mellitus variable (insulin-treated DM vs. non-insulin-treated DM vs. no DM)
33	ORAL	Num	8	X2620F.	3.	T005: B17c2. Treatment for diabetes mellitus: oral
34	DIET	Num	8	X2620F.	3.	T005: B17c3. Treatment for diabetes mellitus: diet

Num	Variable	Type	Len	Format	Informat	Label
35	TREAT_OTH	Num	8	X2620F.	3.	T005: B17c4. Treatment for diabetes mellitus: other
36	treat_sp_cat	Num	8			Treat for diabetes mellitus: other: specify (categorical variable)
37	DM_COMPLIC	Num	8	X2730F.	3.	T005: B17d. Diabetes: Microvascular complications
38	DM_RETINO	Num	8	X2730F.	3.	T005: B17di. Microvascular complications: Retinopathy
39	DM_NEPHRO	Num	8	X2730F.	3.	T005: B17dii. Microvascular complications: Nephropathy
40	DM_NEURO	Num	8	X2730F.	3.	T005: B17diii. Microvascular complications: Neuropathy
41	FRACTURE	Num	8	X2730F.	3.	T005: B18. Bone fracture after the age of 45
42	FRAC_SITE	Num	8	X2672F.	3.	T005: B18a. If YES, specify the site
43	SMOKE	Num	8	X2730F.	3.	T005: C1. Does the subject currently smoke
44	cigs	Num	8	X2602F.	3.	T005: C1a. Avg number of cigarettes a day
45	SMOKE_YRS	Num	8	X2602F.	3.	T005: C1b. Number of years smoking
46	SMOKE_EVER	Num	8	X2730F.	3.	T005: C2. Has subject ever been a smoker
47	QUIT_YRS	Num	8	X2602F.	3.	T005: C2a. How many years since quitting
48	alcohol4_cat	Num	8			How many Drinks do you consume per week (0/1-5/5-10/11+)
49	HEAVY_WK	Num	8	X2602F.	3.	T005: C4a. Exercise: Heavy
50	HEAVY_MIN	Num	8	X2602F.	4.	T005: C4b. Exercise: Heavy: Minutes
51	MED_WK	Num	8	X2602F.	3.	T005: C5a. Exercise: Medium
52	MED_MIN	Num	8	X2602F.	4.	T005: C5b. Exercise: Medium: Minutes
53	LIGHT_WK	Num	8	X2602F.	3.	T005: C6a. Exercise: Light
54	LIGHT_MIN	Num	8	X2602F.	4.	T005: C6b. Exercise: Light: Minutes
55	metsperweek	Num	8	6.2		Activity Level (mets per week)
56	LIVE_ALONE	Num	8	X2730F.	3.	T005: C7. Does the subject currently live alone
57	LIVE_SPOUSE	Num	8	X2730F.	3.	T005: C7a. Does the subject live with a spouse or significant other
58	STAPLE_FOOD	Num	8	X2610F.	3.	T005: C8a. Salt: Staple food
59	SOUP	Num	8	X2610F.	3.	T005: C8b. Salt: Soup
60	MEAT	Num	8	X2610F.	3.	T005: C8c. Salt: Meat
61	VEG	Num	8	X2610F.	3.	T005: C8d. Salt: Vegetables
62	cooking_salt_score	Num	8	2.		Cooking Salt Score
63	SHAKES_SALT	Num	8	X2602F.	3.	T005: C9. How many shakes of salt
64	MEALS_HOME	Num	8	X2608F.	3.	T005: C10. What percent subject's noon/evening meals prepared at home
65	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification

Data Set Name: t006.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	VISIT	Char	4	$4.	$4.	T006: A3. Visit
3	visit_dt1	Num	8			Time between randomization and visit date (years)
4	PULM	Num	8	X2616F.	3.	T006: B2a. Pulmonary
5	CV	Num	8	X2616F.	3.	T006: B3a. Cardiovascular
6	NEURO	Num	8	X2616F.	3.	T006: B4a. Neurological
7	nyha_class_cat	Num	8	NYHA_CLASS_CATFMT.		NYHA class 3&4 vs 1&2
8	height	Num	8			Height in cm
9	weight	Num	8			Weight in kg
10	waistc	Num	8			Waist Circumference in cm
11	HR	Num	8	X2602F.	4.	T006: B9. Heart rate
12	SBP	Num	8	X2602F.	4.	T006: B10a. Systolic blood pressure
13	SBP_METHOD	Num	8	X2687F.	3.	T006: B10b. Systolic blood pressure: Method
14	DBP	Num	8	X2602F.	4.	T006: B11. Diastolic blood pressure
15	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification

Data Set Name: t007_allvisits_bymed.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	VISIT	Char	4	$4.	$4.	VISIT
3	MED_CHANGE	Num	8	X2730F.	3.	T007: B2. Any changes to subject's medication
4	CODED_MED_NAME	Char	80	$80.	$80.	Medication Name (per WHOODE)
5	MEDCAT_WHODDE	Char	100	$100.	$100.	Medication Category (per WHODDE)
6	DOSE	Num	8	X2602F.	8.2	T007: Total daily dose
7	UNITS	Num	8	X2751F.	3.	T007: Units
8	visit_dt1	Num	8			Time from Randomization to visit date (years)

Data Set Name: t007_allvisits_bysub.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	VISIT	Char	4	$4.	$4.	T007: A3. Visit
3	MED_CHANGE	Num	8	X2730F.	3.	T007: B2. Any changes to subject's medication
4	visit_dt1	Num	8			Time from Randomization to visit date (years)
5	ACE_YN	Num	8	NYF.		Use of Angiotensin converting enzyme inhibitor (WHODDE)
6	ARB_YN	Num	8	NYF.		Use of Angiotensin receptor blocker (WHODDE)
7	BB_YN	Num	8	NYF.		Use of Beta-blocker (WHODDE)
8	CCB_YN	Num	8	NYF.		Use of Calcium channel blocker (WHODDE)
9	DIUR_YN	Num	8	NYF.		Use of Diuretic (WHODDE)
10	HYPOG_YN	Num	8	NYF.		Use of Hypoglycemic agent (WHODDE)
11	CVMED_YN	Num	8	NYF.		Use of Other cardiovascular medication - including aspirin, nitrates, statins or warfarin (WHODDE)
12	NONCV_YN	Num	8	NYF.		Use of Non-cardiovascular medication (WHODDE)
13	ACE_ARB_YN	Num	8	NYF.		Use of ACE-I or ARB (WHODDE)
14	ASPIRIN_YN	Num	8	NYF.		Use of Aspirin (WHODDE)
15	NITRATE_YN	Num	8	NYF.		Use of Long-acting nitrate (WHODDE)
16	STATIN_YN	Num	8	NYF.		Use of Statin (WHODDE)
17	WARFARIN_YN	Num	8	NYF.		Use of Warfarin (WHODDE)
18	OTHCVMED_YN	Num	8	NYF.		Use of Other cardiovascular medication - not including aspirin, nitrates, statins or warfarin (WHODDE)
19	LIPIDLOWERING_YN	Num	8	NYF.		Use of Lipid Lowering (WHODDE)
20	OTHER_ANTIHTN_YN	Num	8	NYF.		Use of Other ANTIHTN (WHODDE)
21	SSRI_YN	Num	8	NYF.		Use of Antidepressant (WHODDE)
22	cardiac_meds	Num	8	NYF.		Use of cardiac medications (BB/ACE/ARB/DIUR/aspirin/lipid-lowering)(WHODDE)
23	antiHTN_meds	Num	8	NYF.		Use of blood pressure lowering medication (WHODDE)

Data Set Name: t008.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	VISIT	Char	4	$4.	$4.	T008: A3. Visit
3	LABS_YN	Num	8	X2730F.	3.	T008: B1. Was a blood specimen collected?
4	GLUC_METH	Num	8	X2667F.	3.	T008: B9. Blood Glucose
5	GLUCOSE_FAST	Num	8			Fasting Glucose: Result (mg/dL)
6	GLUCOSE_RAND	Num	8			Random Glucose: Result (mg/dL)
7	CR_mgdl	Num	8			Creatinine: Result (mg/dL)
8	gfr	Num	8			recalculated eGFR
9	labs_dt1	Num	8			Time from Randomization to lab date (years)
10	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification
11	NA_mmolL	Num	8	X2602F.	4.	T008: B3b. NA: Result (mmol/L)
12	K_mmolL	Num	8	X2602F.	5.1	T008: B4b. K: Result (mmol/L)
13	CL_mmolL	Num	8	X2602F.	4.	T008: B5b. CL: Result (mmol/L)
14	CO2_mmolL	Num	8	X2602F.	4.	T008: B6b. CO2: Result (mmol/L)
15	BUN_mgdL	Num	8	X2602F.	6.1	T008: B7b. BUN: Result (mg/dL)
16	GLUCOSE_mgdL	Num	8	X2602F.	6.1	T008: B9b. Glucose: Result (mg/dL)
17	WBC_kuL	Num	8	X2602F.	5.1	T008: B10b. WBC count: Result (k/uL)
18	HCT_p	Num	8	X2602F.	7.2	T008: B11b. Hematocrit: Result (%)
19	HB_gdL	Num	8	X2602F.	6.1	T008: B12b. Hemoglobin: Result (g/dL)
20	PLT_kuL	Num	8	X2602F.	5.	T008: B13b. Platelet Count: Result (k/uL)
21	ALT_UL	Num	8	X2602F.	6.1	T008: B14b. Alanine Aminotransferase: Results (U/L)
22	ALP_UL	Num	8	X2602F.	6.1	T008: B15b. Alkaline Phosphatase: Results (U/L)
23	AST_UL	Num	8	X2602F.	6.1	T008: B16b. Aspartate Aminotransferase: Results (U/L)
24	TBILI_mgdL	Num	8	X2602F.	5.1	T008: B17b. Total Bilirubin: Results (mg/dL)
25	ALB_gdL	Num	8	X2602F.	6.1	T008: B18b. Albumin: Results (g/dL)

Data Set Name: t009.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Random ID
2	VISIT	Char	4	$4.	$4.	T009: A3. Visit
3	URINE_TEST	Num	8	X2730F.	3.	T009: B1. Was a urine sample collected?
4	URINE_DT1	Num	8			Time from Randomization to Urine Collection date (years)
5	urine_val_mgg	Num	8	X2602F.	5.	T009: B3b. Urine Microalbumin/Creatinine Ratio Result (mg/g)
6	PROTEINURIA	Num	8	PROFMT.	3.	T009: B4. What is the urine dipstick measurement of proteinuria?
7	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification

Data Set Name: t010.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	VISIT	Char	4	$4.	$4.	T010: A3. Visit
3	ecg_dt1	Num	8			Time from Randomization to ECG date (years)
4	QRS_DUR	Num	8	X2602F.	4.	T010: B2. QRS Duration
5	HR	Num	8	X2602F.	4.	T010: B3. Heart rate
6	ECG_EVAL	Num	8	X2696F.	3.	T010: B4. Overall evaluation of ECG
7	ECG_AFIB	Num	8	X2730F.	3.	T010: B4a. Atrial fibrillation/Flutter
8	ECG_BBB2	Num	8	NYF.		ECG: Bundle Branch Block - Yes/No indicator
9	ECG_VPR	Num	8	X2730F.	3.	T010: B4c. Ventricular paced rhythm
10	ECG_Q	Num	8	X2730F.	3.	T010: B4d. Pathological Q waves
11	ECG_LVH	Num	8	X2730F.	3.	T010: B4e. Left ventricular hypertrophy
12	ECG_OTH	Num	8	X2730F.	3.	T010: B4f. Other
13	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification

Data Set Name: t011.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Random ID
2	VISIT	Char	4	$4.	$4.	T011: A3. Visit
3	GENDER	Num	8	X2686F.	3.	T011: B3. Gender
4	age_entry	Num	8			Age Entering Study
5	CR_mgdL	Num	8	X2602F.	6.1	T008: B8b. Creatinine: Result (mg/dL)
6	IN_HOSP	Num	8	X2730F.	3.	T011: B6. Did subject have at least one hospital admission
7	IN_BNP	Num	8	X2730F.	3.	T011: B7. Did subject have a brain natriuretic peptide
8	IN_ALL	Num	8	X2730F.	3.	T011: B8. Did subject meet all inclusion criteria
9	EX_ALL	Num	8	X2730F.	3.	T011: B9. Did subject meet none of the exclusion criteria
10	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification
11	drug	Num	8	DRUG2F.		Treatment Group
12	country	Num	8	COUNTRYF.		Country of Origin

Data Set Name: t012.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	VISIT	Char	4	$4.	$4.	T012: A3. Visit
3	visit_dt1	Num	8			Time from Randomization to visit date (years)
4	drug_init	Char	3	$3.	$3.	T012: B2. Initials of person who dispensed study drug
5	BOTTLE_DISP	Num	8	X2602F.	3.	T012: B3. Number of bottles dispensed
6	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification

Data Set Name: t013.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	VISIT	Char	4	$4.	$4.	T013: A3. Visit
3	visit_dt1	Num	8			Time from Randomization to visit date (years)
4	EXAM_YN	Num	8	X2615F.	3.	T013: B1a. Was a physical exam done?
5	PULM	Num	8	X2616F.	3.	T013: B2a. Pulmonary
6	CV	Num	8	X2616F.	3.	T013: B3a. Cardiovascular
7	NEURO	Num	8	X2616F.	3.	T013: B4a. Neurological
8	nyha_class_cat	Num	8	NYHA_CLASS_CATFMT.		NYHA class 3&4 vs 1&2
9	waistc	Num	8			Waist Circumference in cm
10	weight	Num	8			Weight in kg
11	HR	Num	8	X2602F.	4.	T013: B8. Heart rate
12	SBP	Num	8	X2602F.	4.	T013: B9a. Systolic blood pressure
13	SBP_METHOD	Num	8	X2687F.	3.	T013: B9b. Systolic blood pressure: Method
14	DBP	Num	8	X2602F.	4.	T013: B10a. Diastolic blood pressure
15	DYSP_PAROX	Num	8	X2616F.	3.	T013: C1. Paroxysmal nocturnal dyspnea
16	ORTHOPNEA	Num	8	X2616F.	3.	T013: C2. Orthopnea
17	DOE	Num	8	X2616F.	3.	T013: C3. Dyspnea on mild or moderate exertion
18	RALES	Num	8	X2616F.	3.	T013: D1. Any rales post cough
19	JVP	Num	8	X2616F.	3.	T013: D2. Jugular venous pressure (JVP) >= 10 cm H2O
20	LE_EDEMA	Num	8	X2616F.	3.	T013: D3. Lower extremity edema
21	CXR	Num	8	X2616F.	3.	T013: D4. Chest x-ray demonstrating pleural effusion, congestion
22	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification

Data Set Name: t014.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	VISIT	Char	4	$4.	$4.	T014: A3. Visit
3	visit_dt1	Num	8			Time from Randomization to visit date (years)
4	CHF_HOSP	Num	8	X2730F.	3.	T014: B2. Have there been any hospitalizations for management of HF
5	CHF_NUM	Num	8	X2602F.	3.	T014: B2a. Number of hosp. for management of heart failure
6	NEW_ILLNESS	Num	8	X2730F.	3.	T014: B3. Has there been any newly diagnosed illness
7	DM	Num	8	X2730F.	3.	T014: B4. New onset of diabetes mellitus
8	AFIB	Num	8	X2730F.	3.	T014: B5. New onset of atrial fibrillation
9	AFIB_NUM	Num	8	X2602F.	3.	T014: B5a. Number of events with new onset of atrial fibrillation
10	MI	Num	8	X2730F.	3.	T014: B6. New onset of MI (fatal & non-fatal)
11	MI_NUM	Num	8	X2602F.	3.	T014: B6a. Number of events with myocaridal infarction
12	STROKE	Num	8	X2730F.	3.	T014: B7. New onset of stroke (fatal & non-fatal)
13	STROKE_NUM	Num	8	X2602F.	3.	T014: B7a. Number of events with stroke since last visit
14	RENAL	Num	8	X2730F.	3.	T014: B8. Deterioration of renal function
15	RENAL_NUM	Num	8	X2602F.	3.	T014: B8a. Number of events with deterioration of renal function
16	CARD_ARREST	Num	8	X2730F.	3.	T014: B9. Aborted cardiac arrest
17	CA_NUM	Num	8	X2602F.	3.	T014: B9a. Number of events with aborted cardiac arrest
18	CHF	Num	8	X2730F.	3.	T014: B10. New or worsening symptoms of CHF
19	CHF_HOSPS	Num	8	X2730F.	3.	T014: B10a. Hospitalization for New or worsening symptoms of CHF
20	NEWCHF_NUM	Num	8	X2602F.	3.	T014: B10b. Number of events with new or worsening symptoms of CHF
21	EVENT_OTH	Num	8	X2730F.	3.	T014: B11. Other
22	INTERVENTION	Num	8	X2730F.	3.	T014: B12. Have there been any therapeutic interventions
23	MEDICAL	Num	8	X2730F.	3.	T014: B12a. Medication intervention
24	SURGICAL	Num	8	X2730F.	3.	T014: B12b. Surgical intervention
25	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification

Data Set Name: t015.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	VISIT	Char	4	$4.	$4.	T015: A3. Visit
3	visit_dt1	Num	8			Time from Randomization to visit date (years)
4	ADJUSTED	Num	8	X2730F.	3.	T015: B2. Since the last visit, was the study drug dose adjusted
5	ADJUSTED2	Num	8	X2730F.	3.	T015: B2. Was the study dose increased, decreased, or discontinued..
6	ADJUST_TYPE	Num	8	ADJ_TYPE_FMT.	3.	T015: B3. How was the study drug dose adjusted
7	increase_dt3	Num	8			Time from randomization to increase date (years)
8	decrease_dt3	Num	8			Time from randomization to decrease date (years)
9	DECR_HKALEM	Num	8	X2730F.	3.	T015: C3a. Reason for decrease: Hyperkalemia
10	DECR_RF	Num	8	X2730F.	3.	T015: C3b. Reason for decrease: Abnormal renal function
11	DECR_GYNECOM	Num	8	X2730F.	3.	T015: C3c. Reason for decrease: Gynecomastia
12	DECR_REQUEST	Num	8	X2730F.	3.	T015: C3d. Reason for decrease: Subject's request
13	DECR_OTH	Num	8	X2730F.	3.	T015: C3e. Reason for decrease: Other
14	DOSE_ADJUST	Num	8	X2625F.	3.	T015: C4. What was the adjusted dose
15	temp_dt3	Num	8			Time from randomization to temporary discontinuation date (years)
16	RE_INITIATED	Num	8	X2730F.	3.	T015: D2. Was study drug re-initiated prior to this visit
17	reinit_dt3	Num	8			Time from randomization to reinitiation date (years)
18	DOSE_REINIT	Num	8	X2625F.	3.	T015: D3. At what dose was study drug re-initiated
19	BOTTLES	Num	8	X2730F.	3.	T015: E1. Did subject bring in study drug bottles
20	UNOPENED	Num	8	X2602F.	3.	T015: E2. How many unopened bottles did subject bring to this visit?
21	RETURNED	Num	8	X2602F.	3.	T015: E2a. How many unopened bottles were returned to site?
22	EMPTY	Num	8	X2602F.	3.	T015: E3. How many empty bottles did subject bring to this visit?
23	OPENED	Num	8	X2602F.	3.	T015: E3. How many opened bottles did the subject bring to this visit?
24	LOST_EMPTY	Num	8	X2602F.	3.	T015: E3a. How many empty bottles were lost or thrown away
25	UNITS_BOTT1	Num	8	X2743F.	3.	T015: E3a1. Units - Bottle 1
26	NUM_BOTT1	Num	8	X2602F.	4.	T015: E3a2. Number - Bottle 1
27	RETURN_BOTT1	Num	8	X2730F.	3.	T015: E3a3. Returned - Bottle 1
28	UNITS_BOTT2	Num	8	X2743F.	3.	T015: E3b1. Units - Bottle 2
29	NUM_BOTT2	Num	8	X2602F.	4.	T015: E3b2. Number - Bottle 2
30	RETURN_BOTT2	Num	8	X2730F.	3.	T015: E3b3. Returned - Bottle 2
31	UNITS_BOTT3	Num	8	X2743F.	3.	T015: E3c1. Units - Bottle 3
32	NUM_BOTT3	Num	8	X2602F.	4.	T015: E3c2. Number - Bottle 3
33	RETURN_BOTT3	Num	8	X2730F.	3.	T015: E3c3. Returned - Bottle 3

Num	Variable	Type	Len	Format	Informat	Label
34	UNITS_BOTT4	Num	8	X2743F.	3.	T015: E3d1. Units - Bottle 4
35	NUM_BOTT4	Num	8	X2602F.	4.	T015: E3d2. Number - Bottle 4
36	RETURN_BOTT4	Num	8	X2730F.	3.	T015: E3d3. Returned - Bottle 4
37	UNITS_BOTT5	Num	8	X2743F.	3.	T015: E3e1. Units - Bottle 5
38	NUM_BOTT5	Num	8	X2602F.	4.	T015: E3e2. Number - Bottle 5
39	RETURN_BOTT5	Num	8	X2730F.	3.	T015: E3e3. Returned - Bottle 5
40	LOST_UNOPEND	Num	8	X2602F.	3.	T015: E4. How many unopened bottles were lost or thrown away
41	LOST_OPENED	Num	8	X2602F.	3.	T015: E5. How many opened (incl. empty) bottles were lost/thrown away
42	BOTTLE1	Num	8	X2602F.	4.	T015: E5a. Volume: Bottle 1
43	BOTTLE2	Num	8	X2602F.	4.	T015: E5b. Volume: Bottle 2
44	BOTTLE3	Num	8	X2602F.	4.	T015: E5c. Volume: Bottle 3
45	BOTTLE4	Num	8	X2602F.	4.	T015: E5d. Volume: Bottle 4
46	BOTTLE5	Num	8	X2602F.	4.	T015: E5e. Volume: Bottle 5
47	DOSE_NEW	Num	8	X2607F.	3.	T015: E6. Newly prescribed dose
48	PERM_DC	Num	8	X2730F.	3.	T015: E7. Was study drug permanently discontinued
49	perm_Dt3	Num	8			Time from randomization to date drug permanently discontinued (years)
50	PERM_HKALEM	Num	8	X2730F.	3.	T015: E9a. Discontinued: persistent hyperkalemia
51	PERM_LOWEST	Num	8	X2730F.	3.	T015: E9b. Discontinued: Potassium >= 5.5 mmol/L and on lowest dose
52	PERM_RF	Num	8	X2730F.	3.	T015: E9c. Discontinued: Abnormal renal function
53	PERM_INTOLER	Num	8	X2730F.	3.	T015: E9d. Discontinued: Anaphylactoid reaction or intolerance
54	PERM_BREAST	Num	8	X2730F.	3.	T015: E9e. Discontinued: Breast tenderness or enlargement
55	PERM_LABEL	Num	8	X2730F.	3.	T015: E9f. Discontinued: Open label use of aldost. antag. or K-sparing
56	PERM_OTH	Num	8	X2730F.	3.	T015: E9g. Discontinued: Other
57	DISPENSED	Num	8	X2730F.	3.	T015: E10. Additional drug dispensed at this visit
58	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification

Data Set Name: t016.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	VISIT	Char	4	$4.	$4.	T016: A3. Visit
3	LABS_YN	Num	8	X2730F.	3.	T016: B1. Was a blood specimen collected
4	labs_dt1	Num	8			Time from Randomization to date of lab (years)
5	LABS_DOSE	Num	8	X2730F.	3.	T016: B3. Is this a follow-up blood draw based on a dose change
6	NA_mmolL	Num	8	X2602F.	4.	T008: B3b. NA: Result (mmol/L)
7	K_mmolL	Num	8	X2602F.	5.1	T008: B4b. K: Result (mmol/L)
8	CL_mmolL	Num	8	X2602F.	4.	T008: B5b. CL: Result (mmol/L)
9	CO2_mmolL	Num	8	X2602F.	4.	T008: B6b. CO2: Result (mmol/L)
10	BUN_mgdL	Num	8	X2602F.	6.1	T008: B7b. BUN: Result (mg/dL)
11	CR_mgdL	Num	8	X2602F.	6.1	T008: B8b. Creatinine: Result (mg/dL)
12	CHNG_DOSE	Num	8	X2730F.	3.	T016: C1. Was there a change in study drug dose
13	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification

Data Set Name: t017.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	VISIT	Char	4	$4.	$4.	T017: A3. Visit
3	part_dt1	Num	8			Time from Randomization to participation date (years)
4	PART_CHANGE	Num	8	X2713F.	3.	T017: B2. Indicate change in subject participation
5	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification

Data Set Name: t020.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	chf_dt3	Num	8			Time from randomization to CHF event (years)
3	CHF_REAL	Num	8	X2730F.	3.	T020: B1a. CHF event
4	LOCATION	Num	8	X2676F.	3.	T020: B2. Location of the event
5	LOCAT_SP_cat	Num	8	LOCATIONF.		Location of event occurrence: Other
6	SYMPT_TYPE	Num	8	X2692F.	3.	T020: B3a. Please indicate type of symptoms
7	DYSPNEA	Num	8	X2647F.	3.	T020: B3b1. Increasing dyspnea on exertion
8	ORTHOPNEA	Num	8	X2647F.	3.	T020: B3b2. Worsening orthopnea
9	PN_DYSPNEA	Num	8	X2647F.	3.	T020: B3b3. Paroxysmal nocturnal dyspnea
10	FATIGUE	Num	8	X2647F.	3.	T020: B3b4. Increasing fatigue/worsening exercise tolerance
11	MENTAL	Num	8	X2647F.	3.	T020: B3b5. Altered mental status
12	SYMP_UNK	Num	8	X2647F.	3.	T020: B3b6. Unknown
13	SYMP_OTH	Num	8	X2647F.	3.	T020: B3b7. Other
14	WEIGHT_GAIN	Num	8	X2647F.	3.	T020: B4a. Rapid weight gain
15	PULM_EDEMA	Num	8	X2647F.	3.	T020: B4b. Pulmonary edema or rales
16	ELEVATED_JVP	Num	8	X2647F.	3.	T020: B4c. Elevated jugular venous pressure
17	RADIOL_SIGN	Num	8	X2647F.	3.	T020: B4d. Radiologic signs of heart failure
18	PERIPH_EDEMA	Num	8	X2647F.	3.	T020: B4e. Peripheral edema
19	ABDOMINAL	Num	8	X2647F.	3.	T020: B4f. Abdominal distension with ascites
20	S3_GALLOP	Num	8	X2647F.	3.	T020: B4g. S3 Gallop
21	REFLUX	Num	8	X2647F.	3.	T020: B4h. Hepatojugular reflux
22	BNP	Num	8	X2647F.	3.	T020: B4i. Brain natriuretic peptide
23	BNP_VAL	Num	8	X2602F.	5.	T020: B4i1. Brain natriuretic peptide: Value
24	PRO_BNP	Num	8	X2647F.	3.	T020: B4j. N-terminal pro-BNP
25	PROBNP_VAL	Num	8	X2602F.	6.	T020: B4j1. N-terminal pro-BNP: Value
26	SIGN_UNK	Num	8	X2647F.	3.	T020: B4k. Unknown
27	SIGN_OTH	Num	8	X2647F.	3.	T020: B4l. Other
28	IV_YN	Num	8	X2730F.	3.	T020: B5. Did the subject require intravenous therapy
29	VASODILATORS	Num	8	X2647F.	3.	T020: B6a. Vasodilators
30	DIURETICS	Num	8	X2647F.	3.	T020: B6b. Diuretics
31	INOTROPES	Num	8	X2647F.	3.	T020: B6c. Inotropes
32	ULTFILTRA	Num	8	X2647F.	3.	T020: B6d. Ultrafiltration
33	BALLOON_PUMP	Num	8	X2647F.	3.	T020: B6e. Intra-aortic balloon pump
34	ORAL_DIUR	Num	8	X2730F.	3.	T020: B7a. Oral diuretics
35	ACE_ARB	Num	8	X2730F.	3.	T020: B7b. ACE Inhibitors Angiotensin Receptor Blockers (ARB's)

Num	Variable	Type	Len	Format	Informat	Label
36	BB	Num	8	X2730F.	3.	T020: B7c. Beta-blockers
37	SPIRO	Num	8	X2730F.	3.	T020: B7d. Spironolactone (non-study drug)
38	MEDS_OTH	Num	8	X2730F.	3.	T020: B7e. Other
39	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification
40	ADJUD_STATUS	Num	8	ADJUD_STATUS_FMT.	2.	ADJUDICATION STATUS
41	outcome	Num	8			Clinical Outcome ID

Data Set Name: t021.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	renal_dt1	Num	8			Time between Randomization and Renal event date (years)
3	RENAL_WORSE	Num	8	X2730F.	3.	T021: B2. Did the subject have progressive renal insufficiency
4	DOUB_CREAT	Num	8	X2730F.	3.	T021: B2. Doubling of Serum Creatinine
5	CR_UNIT_1	Num	8	X2748F.	3.	T021: B2a. Units
6	CR_RESULT_1	Num	8	X2602F.	6.1	T021: B2b. Results
7	CR_ULN_1	Num	8	X2602F.	6.1	T021: B2c. Upper Limit of Normal
8	PERSIS_RENAL	Num	8	X2733F.	3.	T021: B3. Persistent renal insufficiency
9	CR_DT_21	Num	8			Time between Randomization and Collection date (years)
10	CR_UNIT_2	Num	8	X2748F.	3.	T021: B3b. Units
11	CR_RESULT_2	Num	8	X2602F.	6.1	T021: B3c. Results
12	CR_ULN_2	Num	8	X2602F.	6.1	T021: B3d. Upper Limit of Normal
13	RRT	Num	8	X2654F.	3.	T021: B4. Did the subject require renal replacement therapy
14	REVERSE_CAUS	Num	8	X2730F.	3.	T021: B5. Is there a reversible cause of renal failure
15	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification

Data Set Name: t022.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	mi_dt3	Num	8			Time from Randomization to MI (years)
3	ISCHEMIC	Num	8	X2732F.	3.	T022: B2. Did subject experience ischemic symptoms
4	ECG_CHANGE	Num	8	X2732F.	3.	T022: B3. Were there new ECG changes consistent with infraction
5	CK_MARKERS	Num	8	X2730F.	3.	T022: B4. Were cardiac markers drawn in association with event
6	CK_ND	Num	8	X2647F.	3.	T022: B5a. CK: If not done
7	CK_CODE	Num	8	X2754F.	3.	T022: B5b. CK: Unit codes
8	CK_RESULT	Num	8	X2602F.	6.	T022: B5c. CK: Result
9	CK_LLN	Num	8	X2602F.	6.	T022: B5d. CK: Lower limit
10	CK_ULN	Num	8	X2602F.	6.	T022: B5e. CK: Upper limit
11	CKMB_ND	Num	8	X2647F.	3.	T022: B6a. CK-MB: If not done
12	CKMB_CODE	Num	8	X2754F.	3.	T022: B6b. CK-MB: Unit codes
13	CKMB_RESULT	Num	8	X2602F.	8.1	T022: B6c. CK-MB: Result
14	CKMB_LLN	Num	8	X2602F.	8.1	T022: B6d. CK-MB: Lower limit
15	CKMB_ULN	Num	8	X2602F.	8.1	T022: B6e. CK-MB: Upper limit
16	TROPI_ND	Num	8	X2647F.	3.	T022: B7a. Troponin I: If not done
17	TROPI_CODE	Num	8	X2754F.	3.	T022: B7b. Troponin I: Unit codes
18	TROPI_RESULT	Num	8	X2602F.	7.1	T022: B7c. Troponin I: Result
19	TROPI_LLN	Num	8	X2602F.	7.1	T022: B7d. Troponin I: Lower limit
20	TROPI_ULN	Num	8	X2602F.	7.1	T022: B7e. Troponin I: Upper limit
21	TROPT_ND	Num	8	X2647F.	3.	T022: B8a. Troponin T: If not done
22	TROPT_CODE	Num	8	X2754F.	3.	T022: B8b. Troponin T: Unit codes
23	TROPT_RESULT	Num	8	X2602F.	7.1	T022: B8c. Troponin T: Result
24	TROPT_LLN	Num	8	X2602F.	7.1	T022: B8d. Troponin T: Lower limit
25	TROPT_ULN	Num	8	X2602F.	7.1	T022: B8e. Troponin T: Upper limit
26	REVASC_PROC	Num	8	X2730F.	3.	T022: B5. Event occurred in setting of coronary revascularization
27	ABN_WALL	Num	8	X2730F.	3.	T022: B6. Is there documentation of new wall motion other then septal
28	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification
29	ADJUD_STATUS	Num	8	ADJUD_STATUS_FMT.	2.	ADJUDICATION STATUS
30	outcome	Num	8			Clinical Outcome ID

Data Set Name: t023.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			RANDOMIZED ID
2	DM_DT3	Num	8			Time between randomization and Diabetes Mellitus event date(years)
3	ADA_NONE	Num	8	X2737F.	3.	T023: B2a. None
4	ADA_FG	Num	8	X2737F.	3.	T023: B2b. Fasting Glucose greater than/equal to 126 mg/dl confirmed
5	ADA_NFG	Num	8	X2737F.	3.	T023: B2c. Random(non-fasting) glucose greater than/equal to 200 mg/dL
6	ADA_GTT	Num	8	X2737F.	3.	T023: B2d. 2-Hour post-load glucose greater than/equal to 200 mg/dL
7	LAB1_DT3	Num	8			Time between randomization and collection date (years)
8	GLUC1_UNIT	Num	8	X2744F.	3.	T023: B3b1. Blood Glucose: Units
9	GLUC1_RES	Num	8	X2602F.	6.1	T023: B3b2. Blood Glucose: Result
10	LAB2_DT3	Num	8			Time between randomization and collection date (years)
11	GLUC2_UNIT	Num	8	X2744F.	3.	T023: B4b1. Blood Glucose: Units
12	GLUC2_RES	Num	8	X2602F.	6.1	T023: B4b2. Blood Glucose: Result
13	MEDS_YN	Num	8	X2730F.	3.	T023: B5. Was the subject started on medication, oral hypoglycemic
14	MEDS_DT3	Num	8			Time between randomization and Date medication started (years)
15	MEDS1_NAME_cat	Num	8	MEDS1_NAME_CATF.		First Medication category
16	MEDS1_DOSE	Num	8	X2602F.	8.2	T023: B7b1. Dose
17	MEDS1_UNITS	Num	8	X2752F.	3.	T023: B7c1. Units
18	MEDS1_FREQ	Num	8	X2753F.	3.	T023: B7d1. Frequency
19	MEDS2_DOSE	Num	8	X2602F.	8.2	T023: B7b2. Dose
20	MEDS2_UNITS	Num	8	X2752F.	3.	T023: B7c2. Units
21	MEDS2_FREQ	Num	8	X2753F.	3.	T023: B7d2. Frequency
22	MEDS3_DOSE	Num	8	X2602F.	8.2	T023: B7b3. Dose
23	MEDS3_UNITS	Num	8	X2752F.	3.	T023: B7c3. Units
24	MEDS3_FREQ	Num	8	X2753F.	3.	T023: B7d3. Frequency
25	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification
26	ADJUD_STATUS	Num	8	ADJUD_STATUS_FMT.	2.	ADJUDICATION STATUS
27	outcome	Num	8			Clinical Outcome ID

Data Set Name: t024.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	stroke_dt3	Num	8			Time between stroke even and randomization date (years)
3	APHASIA	Num	8	X2647F.	3.	T024: B2a. Identify the signs: Aphasia
4	SENSORY	Num	8	X2647F.	3.	T024: B2b. Identify the signs: Altered sensation
5	MOTOR	Num	8	X2647F.	3.	T024: B2c. Identify the signs: Focal motor weakness
6	SYMPT_OTH	Num	8	X2647F.	3.	T024: B2d. Identify the signs: Other
7	ONSET_SUDDN	Num	8	X2732F.	3.	T024: B3. Was there a sudden onset of symptoms
8	SYMPT_TIME	Num	8	X2628F.	3.	T024: B4. How long did the symptoms persist
9	CAUSE_OTHER	Num	8	X2732F.	3.	T024: B5. Was there any identifiable cause other than stroke
10	CAUSE_SP_cat	Num	8	CAUSE_SP_CATF.		Was there any identifiable cause other than stroke: Specify (categorical)
11	BRAIN_INF	Num	8	X2732F.	3.	T024: B6. Is there documentation of a brain infarct
12	SCANS	Num	8	X2641F.	3.	T024: B7. How was the brain infarct or hemorrhage documented?
13	SCANS_SP_cat	Num	8	SCANS_SP_CATF.		How was the brain infarct: Specify (categorical
14	NEURO_MD	Num	8	X2732F.	3.	T024: B8. Was the subject seen by a neurologist
15	NEURO_DIAGN	Num	8	X2710F.	3.	T024: B9. What diagnosis was made by the neurologist
16	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification
17	ADJUD_STATUS	Num	8	ADJUD_STATUS_FMT.	2.	ADJUDICATION STATUS
18	outcome	Num	8			Clinical Outcome ID

Data Set Name: t025.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			RANDOMIZED ID
2	afib_dt3	Num	8			Time from Randomization to Atrial Fibrillation event date(years)
3	AFIB_ECG	Num	8	X2730F.	3.	T025: B2. Was atrial fibrillation documented 12-lead electrocardiogram
4	AFIB_PRIOR	Num	8	X2730F.	3.	T025: B2a. Atrial fibrillation documented: If yes
5	AFIB_CAT	Num	8	X2702F.	3.	T025: B2b. Atrial fibrillation documented: If yes: Categorize
6	AFIB_RAND	Num	8	X2730F.	3.	T025: B3. Atrial fibrillation at the time of randomization
7	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification
8	ADJUD_STATUS	Num	8	ADJUD_STATUS_FMT.	2.	ADJUDICATION STATUS
9	outcome	Num	8			Clinical Outcome ID

Data Set Name: t026.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			RANDOMIZED ID
2	aca_dt3	Num	8			Time from Randomization to Aborted Cardiac arrest or Ventricular Tachycardia event date(years)
3	LOC	Num	8	X2732F.	3.	T026: B2. Did the subject suffer a loss of consciousness
4	CPR	Num	8	X2647F.	3.	T026: B3a. CARDIOPULMONARY RESUSCITATION
5	CARDIOVERT	Num	8	X2647F.	3.	T026: B3b. CARDIAC DEFIBRILLATION/CARDIOVERSION
6	RESUS_UNK	Num	8	X2647F.	3.	T026: B3c. UNKNOWN
7	RESUS_OTH	Num	8	X2647F.	3.	T026: B3d. OTHER
8	STATUS	Num	8	X2718F.	3.	T026: B4. Subject status after the subject was resuscitated
9	DISPOSITION	Num	8	X2655F.	3.	T026: B4a. Disposition
10	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification
11	ADJUD_STATUS	Num	8	ADJUD_STATUS_FMT.	2.	ADJUDICATION STATUS
12	outcome	Num	8			Clinical Outcome ID

Data Set Name: t027.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			RANDOMIZED ID
2	hospital_dt3	Num	8			Time from Randomization to hospital date(years)
3	HOSP_YN	Num	8	X2730F.	3.	T027: B2. Is the subject still hospitalized
4	discharge_dt3	Num	8			Time from Randomization to discharge date(years)
5	HOSP_REAS	Num	8	X2644F.	3.	T027: B4. Investigators assessment of pri. reason for hospitalization
6	HOSP_CV	Num	8	X2652F.	3.	T027: B5a. CV Hospitalization (Select one)
7	HOSP_NONCV	Num	8	X2677F.	3.	T027: B5b. Non-CV Hospitalization (Select one)
8	CV_NONE	Num	8	X2612F.	3.	T027: B6a. CV events during hospitalization: None
9	CV_DEATH	Num	8	X2612F.	3.	T027: B6b. CV events during hospitalization: Death
10	CV_MI	Num	8	X2612F.	3.	T027: B6c. CV events during hospitalization: Myocardial Infarction
11	CV_STROKE	Num	8	X2612F.	3.	T027: B6d. CV events during hospitalization: Stroke
12	CV_CHF	Num	8	X2612F.	3.	T027: B6e. CV events during hospitalization: Congestive Heart Failure
13	CV_ACA	Num	8	X2612F.	3.	T027: B6f. CV events during hospitalization: Aborted Cardiac Arrest
14	CV_ARRHYTH	Num	8	X2612F.	3.	T027: B6g. CV events during hospitalization: Arrhythmia
15	CV_PE	Num	8	X2612F.	3.	T027: B6h. CV events during hospitalization: Pulmonary Embolism
16	CV_PROC	Num	8	X2612F.	3.	T027: B6i. CV events during hospitalization: CV Procedure related
17	CV_OTH	Num	8	X2612F.	3.	T027: B6j. CV events during hospitalization: Other CV Event
18	NONCV_NONE	Num	8	X2612F.	3.	T027: B7a. Non CV events during hospitalization: None
19	NONCV_HYPERK	Num	8	X2612F.	3.	T027: B7b. Non CV events during hospitalization: Hyperkalemia
20	NONCV_RENAL	Num	8	X2612F.	3.	T027: B7c. Non CV events during hospitalization: Renal Failure
21	NONCV_PULM	Num	8	X2612F.	3.	T027: B7d. Non CV events during hospitalization: Pulmonary
22	NONCV_GI	Num	8	X2612F.	3.	T027: B7e. Non CV events during hospitalization: Gastrointestinal
23	NONCV_CANCER	Num	8	X2612F.	3.	T027: B7f. Non CV events during hospitalization: Cancer
24	NONCV_OTH	Num	8	X2612F.	3.	T027: B7g. Non CV events during hospitalization: Other Event
25	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification

Data Set Name: t030.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			RANDOMIZED ID
2	VISIT	Char	4	$4.	$4.	T030: A3. Visit
3	CONSENT	Num	8	X2730F.	3.	T030: B2. Did the subject provide consent for additional study visits?
4	term_dt_1	Num	8			Time from Randomization to study end date(years)
5	TERM	Num	8	X2711F.	3.	T030: B3. Primary reason subject ended the study
6	TERM_SP	Char	50	$50.	$50.	T030: B3a. Primary reason subject ended the study: Other
7	VISIT_COMP	Num	8	X2637F.	3.	T030: B4. What is the last study visit the subject completed
8	BOTTLES	Num	8	X2730F.	3.	T030: C1. Were study drug bottles returned at study end?
9	UNOPENED	Num	8	X2602F.	3.	T030: C1a. How many unopened bottles were returned at study end?
10	OPENED	Num	8	X2602F.	3.	T030: C2. How many opened bottles were returned?
11	UNITS_BOTT1	Num	8	X2743F.	3.	T030: C2a3. Units - Bottle 1
12	NUM_BOTT1	Num	8	X2602F.	4.	T030: C2a4. Number - Bottle 1
13	UNITS_BOTT2	Num	8	X2743F.	3.	T030: C2b3. Units - Bottle 2
14	NUM_BOTT2	Num	8	X2602F.	4.	T030: C2b4. Number - Bottle 2
15	UNITS_BOTT3	Num	8	X2743F.	3.	T030: C2c3. Units - Bottle 3
16	NUM_BOTT3	Num	8	X2602F.	4.	T030: C2c4. Number - Bottle 3
17	UNITS_BOTT4	Num	8	X2743F.	3.	T030: C2d3. Units - Bottle 4
18	NUM_BOTT4	Num	8	X2602F.	4.	T030: C2d4. Number - Bottle 4
19	UNITS_BOTT5	Num	8	X2743F.	3.	T030: C2e3. Units - Bottle 5
20	NUM_BOTT5	Num	8	X2602F.	4.	T030: C2e4. Number - Bottle 5
21	EMPTY	Num	8	X2602F.	3.	T030: C3. How many empty bottles were returned at study end?
22	LOST_UNOPEND	Num	8	X2602F.	3.	T030: C3. How many unopened bottles were lost or thrown away
23	LOST_EMPTY	Num	8	X2602F.	3.	T030: C3a. How many empty bottles were lost or thrown away
24	LOST_OPENED	Num	8	X2602F.	3.	T030: C4. How many empty bottles were lost or thrown away
25	PERM_DC	Num	8	X2730F.	3.	T030: C5. Was study drug permanently discontinued
26	perm_dt3	Num	8			Time from Randomization to date of permanent study discontinuation (years)
27	PERM_HKALEM	Num	8	X2730F.	3.	T030: C7a. Discontinued: persistent hyperkalemia
28	PERM_LOWEST	Num	8	X2730F.	3.	T030: C7b. Discontinued: Potassium >= 5.5 mmol/L and on lowest dose
29	PERM_RF	Num	8	X2730F.	3.	T030: C7c. Discontinued: Abnormal renal function
30	PERM_INTOLER	Num	8	X2730F.	3.	T030: C7d. Discontinued: Anaphylactoid reaction or intolerance
31	PERM_BREAST	Num	8	X2730F.	3.	T030: C7e. Discontinued: Breast tenderness or enlargement
32	PERM_LABEL	Num	8	X2730F.	3.	T030: C7f. Discontinued: Open label use of aldost. antag. or K-sparing
33	PERM_OTH	Num	8	X2730F.	3.	T030: C7g. Discontinued: Other
34	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification

Data Set Name: t031.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			RANDOMIZED ID
2	dod1	Num	8			Time from Randomization to Date of death(years)
3	DEATH_LOC	Num	8	X2673F.	3.	T031: B2. Location of death
4	DEATH_CAUSE	Num	8	X2643F.	3.	T031: B4. Investigator's assessment of primary cause
5	DEATH_CV	Num	8	X2691F.	3.	T031: B5a. Cardiovascular death
6	DEATH_NONCV	Num	8	X2704F.	3.	T031: B5b. Non-Cardiovascular death
7	DEATH_EXPECT	Num	8	X2616F.	3.	T031: B7. Was death clinically expected
8	RESUSCITATE	Num	8	X2616F.	3.	T031: B8. Was resuscitation attempted
9	AUTOPSY	Num	8	X2616F.	3.	T031: B9. Was an autopsy/post mortem performed
10	autopsy_dt1	Num	8			Time from Randomization to Date of autopsy (years)
11	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification

Data Set Name: t032.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	VISIT	Char	4	$4.	$4.	T032: A3. Visit
3	CONTACT_YN	Num	8	X2724F.	3.	T032: B1. Sucessful contact made?
4	contact_dt1	Num	8			Time from Randomization to date of Contact(years)
5	CONTACT_WHO	Num	8	X2714F.	3.	T032: B2. Contact made with whom?
6	CONTACT_PROX	Num	8	X2709F.	3.	T032: B2a. Specify proxy contact person.
7	CONTACT_MODE	Num	8	X2703F.	3.	T032: B3. Specify the mode of contact with subject and/or proxy..
8	STATUS_ALIVE	Num	8	X2725F.	3.	T032: B4. Is subject alive at time of contact?
9	alive_dt3	Num	8			Time from Randomization to last date subject known to be alive (years)

Data Set Name: t050.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	VISIT	Char	4	$4.	$4.	T050: A3. Visit
3	AE_REPORT	Num	8	X2682F.	3.	T050: B1. Is this an initial or follow-up AE report
4	AE_NUM	Num	8	X2602F.	3.	T050: B2. AE Identification number
5	AE_ADJ	Num	8	X2730F.	3.	T050: B3. Does this AE represent a new study end point
6	ADJ_REASON	Num	8	X2674F.	3.	T050: B3a. Select a category for this end point
7	AE_CAT	Num	8	X2636F.	3.	T050: C2. Primary category
8	onset_dt3	Num	8			Time from randomization to onset date (years)
9	OUTCOME	Num	8	X2706F.	3.	T050: C4. Outcome
10	RESOLVE_DT3	Num	8			Time from randomization to resolve date (years)
11	death_dt3	Num	8			Time from randomization to death date (years)
12	SEVERITY	Num	8	X2688F.	3.	T050: C6. Severity
13	RELATIONSHIP	Num	8	X2721F.	3.	T050: C7. Relationship to study drug
14	ACTION_NONE	Num	8	X2646F.	3.	T050: C8a. None
15	ACTION_MED	Num	8	X2646F.	3.	T050: C8b. Medical
16	ACTION_SURG	Num	8	X2646F.	3.	T050: C8c. Surgical
17	ACTION_OTH	Num	8	X2646F.	3.	T050: C8d. Other
18	SAE	Num	8	X2730F.	3.	T050: C9. Is this a serious adverse event (SAE)
19	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification

Data Set Name: t051.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	VISIT	Char	4	$4.	$4.	T051: A3. Visit
3	report_dt1	Num	8			Time from randomization to report date (years)
4	age_entry	Num	8			Age of entry into study (years)
5	GENDER	Num	8	GENDFMT.	3.	T051: A6. Gender
6	SAE_REPORT	Num	8	REPORTFMT.	3.	T051: B1. Is this an initial or follow-up SAE report?
7	SAE_NUM	Num	8	3.	3.	T051: B2. AE reference number
8	initial_dt1	Num	8			Time from randomization to initial date (years)
9	ONSET_DT3	Num	8			Time from randomization to onset date (years)
10	UADE	Num	8	NYF.	3.	T051: C3a. Unanticipated Adverse Drug Effect
11	DEATH	Num	8	NYF.	3.	T051: C3b. Death
12	LIFE_THREAT	Num	8	NYF.	3.	T051: C3c. Life-Threatening
13	DISABILITY	Num	8	NYF.	3.	T051: C3d. Persistent/ Significant Disability
14	HOSPITALIZED	Num	8	NYF.	3.	T051: C3e. Initial or Prolonged Hospitalization
15	HOSP_INIT	Num	8	NYF.	3.	T051: C3e1. Initial Hospitalization
16	HOSP_PROL	Num	8	NYF.	3.	T051: C3e2. Prolonged Hospitalization
17	BIRTH_DEFECT	Num	8	NYF.	3.	T051: C3f. Congenital Anomaly/Birth Defect
18	PERM_IMPAIR	Num	8	NYF.	3.	T051: C3g. Permanent impairment/damage of a body function/structure
19	INTERVENTION	Num	8	NYF.	3.	T051: C3h. Intervention to prevent permanent impairment of a body function/structure
20	OUTCOME	Num	8	OUTCOMEFMT.	3.	T051: C4. Outcome
21	RESOLVE_DT3	Num	8			Time from randomization to resolve date (years)
22	DEATH_DT3	Num	8			Time from randomization to death date(years)
23	WITHDRAWN	Num	8	NYF.	3.	T051: C5. Was subject withdrawn from the study?
24	DAILY_DOSE1	Num	8	DOSEFMT.	3.	T051: D1b1. Total Daily Dose
25	start_dt11	Num	8			Time from randomization to start date 1 (years)
26	DOSE_CONT1	Num	8	3.	3.	T051: D1d1. Continuing this dose
27	stop_dt11	Num	8			Time from randomization to stop date 1 (years)
28	DAILY_DOSE2	Num	8	DOSEFMT.	3.	T051: D1b2. Total Daily Dose
29	start_dt21	Num	8			Time from randomization to start date 2 (years)
30	DOSE_CONT2	Num	8	3.	3.	T051: D1d2. Continuing this dose
31	STOP_DT21	Num	8			Time from randomization to stop date 2 (years)
32	DAILY_DOSE3	Num	8	DOSEFMT.	3.	T051: D1b3. Total Daily Dose
33	START_DT31	Num	8			Time from randomization to start date 3 (years)
34	DOSE_CONT3	Num	8	3.	3.	T051: D1d3. Continuing this dose
35	STOP_DT31	Num	8			Time from randomization to stop date 3 (years)

Num	Variable	Type	Len	Format	Informat	Label
36	DAILY_DOSE4	Num	8	DOSEFMT.	3.	T051: D1b4. Total Daily Dose
37	START_DT41	Num	8			Time from randomization to start date 4 (years)
38	DOSE_CONT4	Num	8	3.	3.	T051: D1d4. Continuing this dose
39	STOP_DT41	Num	8			Time from randomization to stop date 4 (years)
40	DAILY_DOSE5	Num	8	DOSEFMT.	3.	T051: D1b5. Total Daily Dose
41	START_DT51	Num	8			Time from randomization to start date 5 (years)
42	DOSE_CONT5	Num	8	3.	3.	T051: D1d5. Continuing this dose
43	STOP_DT51	Num	8			Time from randomization to stop date 5 (years)
44	RELATIONSHIP	Num	8	AERELFMT.	3.	T051: D2. Relationship to Study Drug
45	ACTION	Num	8	SAEACTF.	3.	T051: D3. Action Taken
46	SAE_TEST	Num	8	NYF.	3.	T051: E2. Are there relevant diagnostic test and/or laboratory data to report?
47	SAE_COND	Num	8	NYF.	3.	T051: E3. Are there relevant pre-existing medical conditions to report?
48	SAE_MED	Num	8	NYF.	3.	T051: E4. Are there concomitant medications to report?
49	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification

Data Set Name: t051_conc_rs.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	REPORT_DT1	Num	8			Time from Randomization to report date (years)
3	SAE_REPORT	Num	8	REPORTFMT.	3.	T051: B1. Is this an initial or follow-up SAE report?
4	SAE_NUM	Num	8	3.	3.	T051: B2. AE reference number
5	CODED_MED_NAME	Char	80	$80.	$80.	Medication Name (per WHOODE)
6	MED_CAT	Char	100	$100.	$100.	Medication Category (per WHODDE)
7	MED_DOSE	Num	8	X2602F.	8.2	T051: E4b. Are there concomitant medications to report: Dose
8	MED_UNITS	Num	8	X2750F.	3.	T051: E4c. Are there concomitant medications to report: Units
9	MED_FREQ	Num	8	X2700F.	3.	T051: E4d. Are there concomitant medications to report: Frequency

Data Set Name: t051_test_rs.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	REPORT_DT1	Num	8			Time from Randomization to report date (years)
3	SAE_REPORT	Num	8	REPORTFMT.	3.	T051: B1. Is this an initial or follow-up SAE report?
4	SAE_NUM	Num	8	3.	3.	T051: B2. AE reference number
5	TEST_TYPE	Char	100	$100.	$100.	T051: E2a. SAE test/lab data: Test
6	TEST_RESULT	Char	100	$100.	$100.	T051: E2b. SAE test/lab data: Result
7	TEST_UNITS	Char	100	$100.	$100.	T051: E2c. SAE test/lab data: Units

Data Set Name: t053.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	VISIT	Char	4	$4.	$4.	T053: A3. Visit
3	report_dt1	Num	8			Time from randomization to report date (years)
4	AE_REPORT	Num	8	REPORTFMT.	3.	T053: B1. Is this an initial or follow-up adverse event report?
5	AE_NUM	Num	8	3.	3.	T053: B2. Adverse event identification number
6	initial_dt1	Num	8			Time from randomization to initial date (years)
7	AE_ADJ	Num	8	NYF.	3.	T053: B4. Does this adverse event represent a new study end point in any of the following categories?
8	ADJ_REASON	Num	8	ADJREASONFMT.	3.	T053: B4a. If yes, which study end point?
9	AE_CAT	Num	8	AECATFMT.	3.	T053: C2. Primary Category
10	ONSET_DT3	Num	8			Time from randomization to onset date (years)
11	OUTCOME	Num	8	OUTCOMEFMT.	3.	T053: C4. Outcome
12	RESOLVE_DT3	Num	8			Time from randomization to resolve date (years)
13	DEATH_DT3	Num	8			Time from randomization to death date (years)
14	SEVERITY	Num	8	SEVEREF.	3.	T053: C5. Severity
15	RELATIONSHIP	Num	8	AERELFMT.	3.	T053: C6. Relationship to Study Drug
16	ACTION_NONE	Num	8	CHECKFMT.	3.	T053: C7a. Action take - None
17	ACTION_MED	Num	8	CHECKFMT.	3.	T053: C7b. Action take - Medical
18	ACTION_SURG	Num	8	CHECKFMT.	3.	T053: C7c. Action take - Surgical
19	ACTION_OTH	Num	8	CHECKFMT.	3.	T053: C7d. Action take - Other
20	SAE	Num	8	NYF.	3.	T053: C8. Is this a serious adverse event?
21	WITHDRAWN	Num	8	NYF.	3.	T053: C9. Was subject withdrawn from participating in the study?
22	UADE	Num	8	NYF.	3.	T053: C10a. Unanticipated Adverse Drug Effect
23	DEATH	Num	8	NYF.	3.	T053: C10b. Death
24	LIFE_THREAT	Num	8	NYF.	3.	T053: C10c. Life-Threatening
25	DISABILITY	Num	8	NYF.	3.	T053: C10d. Persistent/ Significant Disability
26	HOSP_INIT	Num	8	NYF.	3.	T053: C10e1. Initial Hospitalization
27	HOSP_PROL	Num	8	NYF.	3.	T053: C10e2. Prolonged Hospitalization
28	BIRTH_DEFECT	Num	8	NYF.	3.	T053: C10f. Congenital Anomaly/Birth Defect
29	PERM_IMPAIR	Num	8	NYF.	3.	T053: C10g. Permanent impairment/damage of a body function/structure
30	INTERVENTION	Num	8	NYF.	3.	T053: C10h. Intervention to prevent permanent impairment of a body function/structure
31	ONSET_DOSE	Num	8	DOSEFMT.	3.	T053: D1b. Study drug information at onset of event - Total daily dose
32	DRG_ONSET_DT1	Num	8			Time from randomization to drug onset date (years)
33	ACTION	Num	8	SAEACTF.	3.	T053: D2. Action Taken

Num	Variable	Type	Len	Format	Informat	Label
34	SAE_TEST	Num	8	NYF.	3.	T053: E2. Are there relevant diagnostic test and/or laboratory data to report?
35	SAE_COND	Num	8	NYF.	3.	T053: E3. Are there relevant pre-existing medical conditions to report?
36	SAE_MED	Num	8	NYF.	3.	T053: E4. Are there concomitant medications to report?
37	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification

Data Set Name: t053_conc_rs.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	REPORT_DT1	Num	8			Time from Randomization to report date (years)
3	AE_REPORT	Num	8	REPORTFMT.	3.	T053: B1. Is this an initial or follow-up adverse event report?
4	AE_NUM	Num	8	3.	3.	T053: B2. Adverse event identification number
5	MEDNAME	Char	50	$50.	$50.	T053: E4a. Concomitant Medications:
6	CODED_MED_NAME	Char	80	$80.	$80.	Medication Name (per WHOODE)
7	MED_CAT	Char	100	$100.	$100.	Medication Category (per WHODDE)

Data Set Name: t053_test_rs.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	REPORT_DT1	Num	8			Time from Randomization to report date (years)
3	AE_REPORT	Num	8	REPORTFMT.	3.	T053: B1. Is this an initial or follow-up adverse event report?
4	AE_NUM	Num	8	3.	3.	T053: B2. Adverse event identification number
5	TEST_TYPE	Char	100	$100.	$100.	T053: E2a. Test
6	TEST_RESULT	Char	100	$100.	$100.	T053: E2b. Result
7	TEST_UNITS	Char	100	$100.	$100.	T053: E2c. Units

Data Set Name: t070.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	site_dt3	Num	8			Time from randomization to Site Reported Date (years)
3	AE_NUM	Num	8	X2602F.	3.	T070: A6. Adverse Event #
4	UN_HOSP	Num	8	X2730F.	3.	T070: B1. Unexpected hospitalization
5	SYMPT_HF	Num	8	X2730F.	3.	T070: B2. Were there symptoms of HF? (check all that apply)
6	DYSPNEA_EXE	Num	8	X2621F.	3.	T070: B2a. Increasing dyspnea on exertion
7	ORTHOPNEA	Num	8	X2621F.	3.	T070: B2b. Worsening orthopnea
8	NOCT_DYSPNEA	Num	8	X2621F.	3.	T070: B2c. Paroxysmal nocturnal dyspnea
9	INC_FATIGUE	Num	8	X2621F.	3.	T070: B2d. Increasing fatigue/decreasing exercise tolerance
10	ALT_MENTAL	Num	8	X2621F.	3.	T070: B2e. Altered mental state
11	OTHER_SYMPT	Num	8	X2621F.	3.	T070: B2f. Other
12	SIGNS_HF	Num	8	X2730F.	3.	T070: B3. Were there signs of HF? (Check all that apply)
13	PERI_EDEMA	Num	8	X2621F.	3.	T070: B3a. Peripheral Edema
14	ELEV_VENOUS	Num	8	X2621F.	3.	T070: B3b. Elevated juglar venous pressure
15	RADIO_SIGNS	Num	8	X2621F.	3.	T070: B3c. Radiological signs of heart failure
16	INC_ABD_DIST	Num	8	X2621F.	3.	T070: B3d. Increasing abdominal distension or ascites
17	PULM_EDEMA	Num	8	X2621F.	3.	T070: B3e. Pulmonary edema or rales
18	WEIGHT_GAIN	Num	8	X2621F.	3.	T070: B3f. Rapid weight gain
19	HEPAT_REFLUX	Num	8	X2621F.	3.	T070: B3g. Heptatojuglar reflux
20	S3_GALLOP	Num	8	X2621F.	3.	T070: B3h. S3 Gallop
21	ELEV_BNP	Num	8	X2621F.	3.	T070: B3i. Elevated BNP or N-Terminal pro-BNP
22	OTHER_SIGN	Num	8	X2621F.	3.	T070: B3j. Other
23	IV_THERAPY	Num	8	X2730F.	3.	T070: B4. Did the subject require IV therapy? (Check all that apply)
24	VASODILATORS	Num	8	X2621F.	3.	T070: B4a. Vasodilators
25	FLUID_REMOVE	Num	8	X2621F.	3.	T070: B4b. Mechanical Fluid Removal
26	DIURETICS	Num	8	X2621F.	3.	T070: B4c. Diuretics
27	INOTOROPES	Num	8	X2621F.	3.	T070: B4d. Inotoropes
28	IABP	Num	8	X2621F.	3.	T070: B4e. IABP
29	CRITERIA	Num	8	X2609F.	3.	T070: B5. TOPCAT criteria met?
30	DOC_SUFFIC	Num	8	X2657F.	3.	T070: B5a. Documentation Sufficient
31	cec_dt3	Num	8			Time from randomization to CEC date (years)
32	CEC_ID	Num	8	X2648F.	3.	T070: C1. CEC Identified
33	PHYS_SIG	Char	60	$60.	$60.	T070: C3. Physician Reviewer Signature
34	phys_sig_dt1	Num	8			Time from randomization to Physician Reviewer Signature date (years)
35	CEC_SIG	Char	60	$60.	$60.	T070: C4. CEC Administrative Signature
36	cec_sig_dt1	Num	8			Time from randomization to administrative signature date (years)

Num	Variable	Type	Len	Format	Informat	Label
37	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification
38	outcome	Num	8			Clinical Outcome ID

Data Set Name: t072.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	site_dt3	Num	8			Time from randomization to site date (years)
3	AE_NUM	Num	8	X2602F.	3.	T072: A6. Adverse Event #
4	SYMP_ISC	Num	8	X2730F.	3.	T072: B1. Symptoms consistent with ischemia?
5	ECG_CHANGES	Num	8	X2730F.	3.	T072: B2. ECG Changes consistent with TOPCAT MI?
6	WAVES	Num	8	X2648F.	3.	T072: B2a. New significant Q waves
7	SEG_WAV	Num	8	X2648F.	3.	T072: B2b. Evolving ST-segment
8	DEV_BLOCK	Num	8	X2648F.	3.	T072: B2c. Development of new left bundle branch block.
9	ST_SEGM	Num	8	X2648F.	3.	T072: B2d. ST segment elevation
10	CARD_CRIT	Num	8	X2730F.	3.	T072: B3. Cardiac Markers meeting
11	TROP_CRIT	Num	8	X2648F.	3.	T072: B3a. Troponin>=2xULN (for necrosis)
12	CKMB_CRIT	Num	8	X2648F.	3.	T072: B3b. CKMB>=2x ULN
13	CK_CRIT	Num	8	X2648F.	3.	T072: B3c. Serial CK
14	PCI_CRIT	Num	8	X2648F.	3.	T072: B3d. Post PCI
15	CABG_CRIT	Num	8	X2648F.	3.	T072: B3e. Post CABG
16	ABNO_CRIT	Num	8	X2648F.	3.	T072: B3f. Post CABG, maker not drawn
17	SYMP_HF	Num	8	X2730F.	3.	T072: B4. Any signs, symptoms, or treatment of HF?
18	MI_CRIT	Num	8	X2729F.	3.	T072: B5. MI criteria met?
19	DOC_SUFFIC	Num	8	X2657F.	3.	T072: B5a. Documentation Sufficient
20	EVENT_DT	Num	8	X2708F.	3.	T072: B6. If criteria met, indicate which date of event (site reported or CEC adjudicated)
21	cec_dt3	Num	8			Time from randomization to CEC site date (years)
22	CEC_ID	Num	8	X2648F.	3.	T072: C1. CEC Identified
23	phys_sig_dt1	Num	8			Time from randomization to physician signature date (years)
24	cec_sig_dt1	Num	8			Time from randomization to CEC signature date (years)
25	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification
26	outcome	Num	8			Clinical Outcome ID

Data Set Name: t073.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	site_dt3	Num	8			Time from Randomization to site date (years)
3	AE_NUM	Num	8	X2602F.	3.	T073: A6. Adverse Event #
4	GLUCOSE_TYPE	Num	8	X2648F.	3.	T073: B1a. Blood glucose ADA criteria for diabetes?
5	FBS	Num	8	X2648F.	3.	T073: B1a1. Two FBS on separate days
6	RAND_GLUC	Num	8	X2648F.	3.	T073: B1a2. Random glucose and subsequent FBS
7	POST_GLUC	Num	8	X2648F.	3.	T073: B1a3. Post load glucose after oral tolerance test
8	ORAL_AGENTS	Num	8	X2648F.	3.	T073: B1b. The initiation and use of oral hypoglycemic agents
9	DIABETE_CRIT	Num	8	X2727F.	3.	T073: B2. New Onset Diabetes Mellitus?
10	DOC_SUFFIC	Num	8	X2657F.	3.	T073: B2a. Documentation Sufficient
11	EVENT_DT	Num	8	X2708F.	3.	T073: B3. If criteria met, indicate which date of event (site reported or CEC adjudicated)
12	cec_dt3	Num	8			Time from randomization to CEC (years)
13	phys_sig_dt1	Num	8			Time from randomization to physician signature date (years)
14	cec_sig_dt1	Num	8			Time from randomization to CEC signature date (years)
15	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification
16	outcome	Num	8			Clinical Outcome ID

Data Set Name: t074.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	site_dt3	Num	8			Time from Randomization to site date (years)
3	AE_NUM	Num	8	X2602F.	3.	T074: A6. Adverse Event #
4	FOCAL	Num	8	X2730F.	3.	T074: B1. Focal neurological deficit?
5	FOCAL_REVERS	Num	8	X2669F.	3.	T074: B1a. Type of focal neurological deficit?
6	STROKE_CRIT	Num	8	X2728F.	3.	T074: B2. Stroke criteria met?
7	STROKE_TYPE	Num	8	X2670F.	3.	T074: B2a. Stroke Type
8	DOC_SUFFIC	Num	8	X2657F.	3.	T074: B2b. Documentation Sufficient
9	EVENT_DT	Num	8	X2708F.	3.	T074: B3. If criteria met, indicate which date of event (site reported or CEC adjudicated)
10	cec_dt3	Num	8			Time from randomization to CEC (years)
11	CEC_ID	Num	8	X2648F.	3.	T074: C1. CEC Identified
12	phys_sig_dt1	Num	8			Time from randomization to physician signature date (years)
13	cec_sig_dt1	Num	8			Time from randomization to CEC signature date (years)
14	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification
15	outcome	Num	8			Clinical Outcome ID

Data Set Name: t075.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	site_dt3	Num	8			Time from Randomization to site date (years)
3	AE_NUM	Num	8	X2602F.	3.	T075: A6. Adverse Event #
4	DOC_SUFFIC	Num	8	X2657F.	3.	T075: B1a. Documentation Sufficient
5	EVENT_DT	Num	8	X2708F.	3.	T075: B2. If criteria met, indicate which date of event (site reported or CEC adjudicated)
6	cec_dt3	Num	8			Time from randomization to CEC (years)
7	CEC_ID	Num	8	X2648F.	3.	T075: C1. CEC Identified
8	phys_sig_dt1	Num	8			Time from randomization to physician signature date (years)
9	cec_sig_dt1	Num	8			Time from randomization to CEC signature date (years)
10	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification
11	AFIB_CRIT	Num	8	X2726F.	3.	T075: B1. Atrial Fibrillation criteria met?
12	outcome	Num	8			Clinical Outcome ID

Data Set Name: t076.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	site_dt3	Num	8			Time from Randomization to site date (years)
3	AE_NUM	Num	8	X2602F.	3.	T076: A6. Adverse Event #
4	EVENT_TYPE	Num	8	X2629F.	3.	T076: B1. Event Type? (Select only one.)
5	ACA_CRIT	Num	8	X2723F.	3.	T076: B2. TOPCAT Aborted Cardiac Arrest Criteria Met?
6	DOC_SUFFIC	Num	8	X2657F.	3.	T076: B2a. Documentation Sufficient
7	EVENT_DT	Num	8	X2708F.	3.	T076: B2. If criteria met, indicate which date of event (site reported or CEC adjudicated)
8	cec_dt3	Num	8			Time from randomization to CEC (years)
9	CEC_ID	Num	8	X2648F.	3.	T076: D1. CEC Identified
10	phys_sig_dt1	Num	8			Time from randomization to physician signature date (years)
11	cec_sig_dt1	Num	8			Time from randomization to CEC signature date (years)
12	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification
13	outcome	Num	8			Clinical Outcome ID

Data Set Name: t079.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	site_dt3	Num	8			Time from Randomization to site date (years)
3	AE_NUM	Num	8	X2602F.	3.	T079: A6. Adverse Event #
4	DEATH_CAUSE	Num	8	X2642F.	3.	T079: B1. Indicate primary cause of Death: (Select only one response)
5	CV_DEATH	Num	8	X2668F.	3.	T079: B2. CV Death specify: (Select only one response)
6	SUD_SPE	Num	8	X2722F.	3.	T079: B2a. Specify Sudden Death:
7	STROKE_SPE	Num	8	X2671F.	3.	T079: B2b. Specify Fatal Stroke:
8	CV_SPE	Num	8	X2640F.	3.	T079: B2c. Specify CV Procedural:
9	NONCV_DEATH	Num	8	X2681F.	3.	T079: B3. Non-CV Death Specify: (Select only one response)
10	DATE_DEATH	Num	8	X2708F.	3.	T079: B4. Indicate which date of death (site reported or CEC adjudicated)
11	cec_dt3	Num	8			Time from randomization to CEC (years)
12	CEC_ID	Num	8	X2648F.	3.	T079: C1. CEC Identified
13	phys_sig_dt1	Num	8			Time from randomization to physician signature date (years)
14	cec_sig_dt1	Num	8			Time from randomization to CEC signature date (years)
15	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification

Data Set Name: t080.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	VISIT	Char	4	$4.	$4.	T080: A3. Visit
3	between_dt1	Num	8			Time from randomization to date when study drug was returned (years)
4	UNOPENED	Num	8	X2602F.	3.	T080: B3. How many unopened bottles were returned
5	OPENED	Num	8	X2602F.	3.	T080: B4. How many opened bottles were returned?
6	UNITS_BOTT1	Num	8	X2743F.	3.	T080: B4a3. Units - Bottle 1
7	NUM_BOTT1	Num	8	X2602F.	4.	T080: B4a4. Number - Bottle 1
8	UNITS_BOTT2	Num	8	X2743F.	3.	T080: B4b3. Units - Bottle 2
9	NUM_BOTT2	Num	8	X2602F.	4.	T080: B4b4. Number - Bottle 2
10	UNITS_BOTT3	Num	8	X2743F.	3.	T080: B4c3. Units - Bottle 3
11	NUM_BOTT3	Num	8	X2602F.	4.	T080: B4c4. Number - Bottle 3
12	UNITS_BOTT4	Num	8	X2743F.	3.	T080: B4d3. Units - Bottle 4
13	NUM_BOTT4	Num	8	X2602F.	4.	T080: B4d4. Number - Bottle 4
14	UNITS_BOTT5	Num	8	X2743F.	3.	T080: B4e3. Units - Bottle 5
15	NUM_BOTT5	Num	8	X2602F.	4.	T080: B4e4. Number - Bottle 5
16	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification

Data Set Name: t081.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	VISIT	Char	4	$4.	$4.	T081: A3. Visit
3	DISPENSED	Num	8	X2730F.	3.	T081: B1. Was study drug dispensed between visits?
4	between_dt1	Num	8			Time from randomization to date when study drug was dispensed (years)
5	BOTTLE_DISP	Num	8	X2602F.	3.	T081: B4. Number of bottles dispensed
6	RETURNED	Num	8	X2730F.	3.	T081: B6. Was study drug returned by the subject between visits?
7	VER_ID	Char	1	$1.	$1.	Case report form (CRF) version identification

Data Set Name: tonometry.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	ID	Num	8			Randomized ID
2	visit	Char	8	$8.	$8.	visit
3	study_date1	Num	8			Time from randomization to date of tonometry (years)
4	central_sbp	Num	8			Central Systolic BP (Sphygmocor)
5	central_dbp	Num	8			Central Diastolic BP (Sphygmocor)
6	central_pp	Num	8			Central pulse pressure (Sphygmocor)
7	ap	Num	8			Central augmentation pressuer (Sphygmocor)
8	p1	Num	8			Derived P1 Height (Central SBP- Augmentation Pressure)
9	aix_hr75	Num	8			Augmentation Index (Sphygmocor, normalized for HR 75 bpm)
10	aix	Num	8			Augmentation Index at reported HR (Sphygmocor)
11	hr	Num	8			Heart Rate at time of tonometry (Sphygmocor)
12	peripheral_sbp	Num	8			Brachial systolic BP at time of tonometry
13	peripheral_dbp	Num	8			Brachial diastolic BP at time of tonometry
14	peripheral_pp	Num	8			Brachial pulse pressure at time of tonometry
15	pp_amp	Num	8			Pulse Pressure Amplification
16	cf	Num	8			Carotid - Femoral Pulse Wave Velocity
17	pwa	Num	8			Pulse Wave Analysis Data Available
18	pwv	Num	8			Pulse Wave Velocity Data Available