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