Data Set Name: a_duplex.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	AD_PER	Num	8	A2. Was an adequate arterial duplex of the aorta and index leg performed within 3 months of patient evaluation
6	AD_DAYSRND	Num	8	Days since randomzation - A2a. Date of Arterial Duplex

Data Set Name: ae.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	AE_NUM	Num	8	B1. Event Number
6	AE_TERM	Char	250	B2. Event Term
7	SURG_COMP_YN	Num	8	B5. Is this event a surgical complication?
8	ENDO_COMP_YN	Num	8	B6. Is this event an endovascular complication?
9	UNANTICIPATE	Num	8	B7. Is this event an unanticipated problem?
10	UNEXPECTED	Num	8	B7a. <i><U>Unexpected in nature, severity, or frequency</U> </I> (i.e. not described in study-related documents such as the IRB-approved protocol or consent form, the investigators brochure, etc)
11	RELATED	Num	8	B7b. <I><U>Related or possibly related to participation in the research</U></I> (i.e. possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research)
12	GREAT_RISK	Num	8	B7c. <i><U>Suggests that the research places subjects or others at greater risk of harm</U> </I> (including physical, psychological, economic, or social harm).
13	SEVERITY	Num	8	B8. Severity
14	SAE	Num	8	B9. Is this a Serious Adverse Event (SAE)?
15	DEATH	Num	8	B9a. Results in death
16	LIFE_THREAT	Num	8	B9b. Immediately Life-threatening event
17	PROLONG_HOSP	Num	8	B9c. Requires hospitalization or prolongation of existing in-patient hospitalization (initial hospitalization for study surgery will not be considered an adverse event or serious adverse event).
18	DISABLE	Num	8	B9d. Results in a persistent or significant disability/incapacitation
19	CONGENTIAL_DEF	Num	8	B9e. Is a congenital anomaly/birth defect
20	MED_EVENT	Num	8	B9f. Is an important medical event defined as a new event likely to affect the safety of the subjects in the trial.
21	RELATIONSHIP	Num	8	B10. Relationship to index procedure:
22	OUTCOME	Num	8	B11. Outcome:
23	MYO_INFAR	Num	8	B5. Is this event a myocardial infarction?
24	STROKE	Num	8	B6. Is this event a stroke?
25	STROKE_CLASS	Num	8	B6a. Stroke classification:
26	MAJOR_REINT	Num	8	B7. Is this event a major re-intervention?
27	RELAT_DEVICE	Num	8	B14. Is the event related to the device implanted during the index procedure?
28	AMPUTATION	Num	8	B15. Did the event result in an amputation?
29	REINT_ADJ	Num	8	DCC ONLY: Is this event a potential first major re-intervention for adjudication?
30	MI_STROKE_ADJ	Num	8	DCC ONLY: Does this event require adjudication (MI or Stroke)?
31	FMRI_ADJ1	Char	1	Trigger Adjudication Form 1 (Tsai)

Num	Variable	Type	Len	Label
32	FMRI_ADJ2	Char	1	Trigger Adjudication Form 2 (Sheahan)
33	FMRI_ADJ3	Char	1	Trigger Adjudication Form 3 (Ouriel)
34	MI_ADJ	Num	8	DCC ONLY: Does this event require adjudication as an MI?
35	MI_ADJUD	Num	8	DCC ONLY: Does this event require adjudication as an MI?
36	MI_ADJ1	Char	1	Trigger Adjudication Form 1 (Montgomery)
37	MI_ADJ2	Char	1	Trigger Adjudication Form 2 (Tsai)
38	MI_ADJ3	Char	1	Trigger Adjudication Form 3 (Ouriel)
39	STROKE_ADJ	Num	8	DCC ONLY: Does this event require adjudication as a stroke?
40	STROKE_ADJ1	Char	1	Trigger Adjudication Form 1 (Mullen)
41	STROKE_ADJ2	Char	1	Trigger Adjudication Form 2 (Sheahan)
42	STROKE_ADJ3	Char	1	Trigger Adjudication Form 3 (Ouriel)
43	UNIQUE_ID	Num	8	Adjudication Event Unique ID
44	BYPASS_GRAFT	Num	8	B7a. New Bypass graft
45	JUMP_GRAFT	Num	8	B7b. Jump/interposition graft revision
46	SURGICAL_THROMB	Num	8	B7c. Surgical thrombectomy
47	THROMBOLYSIS	Num	8	B7d. Thrombolysis (pharmacologic or mechanical)
48	LLT_CODE	Char	1500	LLT_CODE
49	LLT_NAME	Char	1500	LLT_NAME
50	PT_CODE	Char	1500	PT_CODE
51	PT_TERM	Char	1500	PT_TERM
52	HLT_CODE	Char	1500	HLT_CODE
53	HLT_TERM	Char	1500	HLT_TERM
54	HLGT_CODE	Char	1500	HLGT_CODE
55	HLGT_TERM	Char	1500	HLGT_TERM
56	SOC_CODE	Char	1500	SOC_CODE
57	SOC_TERM	Char	1500	SOC_TERM
58	ONSET_DAYSRND	Num	8	Days since randomization - B3. Onset Date
59	REPORT_DAYSRND	Num	8	Days since randomization - B4. Adverse Event Initial report
60	RESOLU_DAYSRND	Num	8	Days since randomization - B16a. Date of resolution, clinical stability or death
61	AWARE_DAYSRND	Num	8	Days since randomization - B4a. Date Site became aware of event

Data Set Name: ae_fu.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	AE_TERM	Char	250	B2. Event Term
6	SURG_COMP_YN	Num	8	B5. Is this event a surgical complication?
7	ENDO_COMP_YN	Num	8	B6. Is this event an endovascular complication?
8	UNANTICIPATE	Num	8	B7. Is this event an unanticipated problem?
9	UNEXPECTED	Num	8	B7a. <i><U>Unexpected in nature, severity, or frequency</U> </I> (i.e. not described in study-related documents such as the IRB-approved protocol or consent form, the investigators brochure, etc)
10	RELATED	Num	8	B7b. <I><U>Related or possibly related to participation in the research</U></I> (i.e. possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research)
11	GREAT_RISK	Num	8	B7c. <i><U>Suggests that the research places subjects or others at greater risk of harm</U> </I> (including physical, psychological, economic, or social harm).
12	SEVERITY	Num	8	B8. Severity
13	SAE	Num	8	B9. Is this a Serious Adverse Event (SAE)?
14	DEATH	Num	8	B9a. Results in death
15	LIFE_THREAT	Num	8	B9b. Immediately Life-threatening event
16	PROLONG_HOSP	Num	8	B9c. Requires hospitalization or prolongation of existing in-patient hospitalization (initial hospitalization for study surgery will not be considered an adverse event or serious adverse event).
17	DISABLE	Num	8	B9d. Results in a persistent or significant disability/incapacitation
18	CONGENTIAL_DEF	Num	8	B9e. Is a congenital anomaly/birth defect
19	MED_EVENT	Num	8	B9f. Is an important medical event defined as a new event likely to affect the safety of the subjects in the trial.
20	RELATIONSHIP	Num	8	B10. Relationship to index procedure:
21	OUTCOME	Num	8	B11. Outcome:
22	MYO_INFAR	Num	8	B5. Is this event a myocardial infarction?
23	STROKE	Num	8	B6. Is this event a stroke?
24	STROKE_CLASS	Num	8	B6a. Stroke classification:
25	MAJOR_REINT	Num	8	B7. Is this event a major re-intervention?
26	RELAT_DEVICE	Num	8	B14. Is the event related to the device implanted during the index procedure?
27	AMPUTATION	Num	8	B15. Did the event result in an amputation?
28	REINT_ADJ	Num	8	DCC ONLY: Is this event a potential first major re-intervention for adjudication?
29	MI_STROKE_ADJ	Num	8	DCC ONLY: Does this event require adjudication (MI or Stroke)?
30	BYPASS_GRAFT	Num	8	B7a. Bypass graft
31	JUMP_GRAFT	Num	8	B7b. Jump/Interposition graft revision

Num	Variable	Type	Len	Label
32	SURGICAL_THROMB	Num	8	B7c. Surgical Thrombectomy
33	THROMBOLYSIS	Num	8	B7d. Thrombolysis (pharmacologic or mechanical)
34	LLT_CODE	Char	1500	LLT_CODE
35	LLT_NAME	Char	1500	LLT_NAME
36	PT_CODE	Char	1500	PT_CODE
37	PT_TERM	Char	1500	PT_TERM
38	HLT_CODE	Char	1500	HLT_CODE
39	HLT_TERM	Char	1500	HLT_TERM
40	HLGT_CODE	Char	1500	HLGT_CODE
41	HLGT_TERM	Char	1500	HLGT_TERM
42	SOC_CODE	Char	1500	SOC_CODE
43	SOC_TERM	Char	1500	SOC_TERM
44	REPORT_DAYSRND	Num	8	Days since randomization - B4. Adverse Event Follow-Up report
45	RESOLU_DAYSRND	Num	8	Days since randomization - B11a. Date of resolution, clinical stability or death

Data Set Name: amp.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	AMP_LEVEL	Num	8	B2. Level of amputation
6	AMP_LEG	Num	8	B3. Which leg had the amputation?
7	PLANNED_YN	Num	8	B2a. Was the amputation planned at the time of consent?
8	AMP_DAYSRND	Num	8	Days since randomization - B1. Date of amputation

Data Set Name: angio.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	PRIOR_ANG_YN	Num	8	A2. Was an adequate angiogram of aorta and index leg performed within 3 months of patient evaluation?
6	CTA_YN	Num	8	A3. Was an adequate CTA of the aorta and index leg performed within 3 months of patient evaluation?
7	MRA_YN	Num	8	A4. Was an adequate MRA of the aorta and index leg performed within 3 months of patient evaluation?
8	IMAGE	Char	4000	A5. Which imaging studies were used to evaluate study criteria?
9	NUM_SEG	Num	8	B1. How many segments show >50% stenosis?
10	SEGMENT_1	Num	8	Segment 1
11	DEGREE_1	Num	8	Worst degree of stenosis in this segment 1
12	SEGMENT_2	Num	8	Segment 2
13	DEGREE_2	Num	8	Worst degree of stenosis in this segment 2
14	SEGMENT_3	Num	8	Segment 3
15	DEGREE_3	Num	8	Worst degree of stenosis in this segment 3
16	SEGMENT_4	Num	8	Segment 4
17	DEGREE_4	Num	8	Worst degree of stenosis in this segment 4
18	SEGMENT_5	Num	8	Segment 5
19	DEGREE_5	Num	8	Worst degree of stenosis in this segment 5
20	SEGMENT_6	Num	8	Segment 6
21	DEGREE_6	Num	8	Worst degree of stenosis in this segment 6
22	SEGMENT_7	Num	8	Segment 7
23	DEGREE_7	Num	8	Worst degree of stenosis in this segment 7
24	SEGMENT_8	Num	8	Segment 8
25	DEGREE_8	Num	8	Worst degree of stenosis in this segment 8
26	SEGMENT_9	Num	8	Segment 9
27	DEGREE_9	Num	8	Worst degree of stenosis in this segment 9
28	SEGMENT_10	Num	8	Segment 10
29	DEGREE_10	Num	8	Worst degree of stenosis in this segment 10
30	SEGMENT_11	Num	8	Segment 11
31	DEGREE_11	Num	8	Worst degree of stenosis in this segment 11
32	SEGMENT_12	Num	8	Segment 12
33	DEGREE_12	Num	8	Worst degree of stenosis in this segment 12
34	SEGMENT_13	Num	8	Segment 13

Num	Variable	Type	Len	Label
35	DEGREE_13	Num	8	Worst degree of stenosis in this segment 13
36	SEGMENT_14	Num	8	Segment 14
37	DEGREE_14	Num	8	Worst degree of stenosis in this segment 14
38	SEGMENT_15	Num	8	Segment 15
39	DEGREE_15	Num	8	Worst degree of stenosis in this segment 15
40	SEGMENT_16	Num	8	Segment 16
41	DEGREE_16	Num	8	Worst degree of stenosis in this segment 16
42	SEGMENT_17	Num	8	Segment 17
43	DEGREE_17	Num	8	Worst degree of stenosis in this segment 17
44	SEGMENT_18	Num	8	Segment 18
45	DEGREE_18	Num	8	Worst degree of stenosis in this segment 18
46	STENT_BSLN	Num	8	B2. Are there any pre-existing arterial stents in the index leg with <30% stenosis?
47	STENT_FU	Num	8	B2. Were any stents visualized?
48	STENT_LOC	Char	4000	B2a. Please note the location(s) of stent
49	TASC_II_IO	Num	8	B3. For iliac occlusive disease in the index leg, please describe TASC II classification:
50	TASC_II_FP	Num	8	B4. For femoral-popliteal occlusive disease in the index leg, please describe TASC II classification:
51	PIAG_YN	Num	8	B5. Is there a patent inflow arterial graft?
52	PIAG	Num	8	B5a. If yes, please choose type:
53	PIAG_SP	Char	4000	B5b. If other, specify:
54	GRAFT_VIS	Num	8	B6. Is an infrainquinal bypass graft visualized?
55	GRAFT_ORIG	Num	8	B6a. Proximal origin
56	GRAFT_RECP	Num	8	B6b. Recipient artery
57	GRAFT_STEN	Num	8	B6c. Is there >50% stenosis in the graft?
58	GRAFT_STEN_LOC	Char	4000	B6c1. Location(s) of stenosis
59	ENDO_AORT_INT	Num	8	B7. Was an endovascular aortoiliac intervention performed on the index leg?
60	ENDO_AORT_LOC	Char	4000	B7a. If yes, specify location(s):
61	ENDO_AORT_MET	Char	4000	B7b. If yes, specify method(s):
62	BSLN_ANGIO_DAYSRND	Num	8	Days since randomization - A2a. Date of Angiogram
63	CTA_DAYSRND	Num	8	Days since randomization - A3a. Date of CTA
64	MRA_DAYSRND	Num	8	Days since randomization - A4a. Date of MRA
65	FU_ANGIO_DAYSRND	Num	8	Days since randomization - A2. Date of Follow-up Angiogram

Data Set Name: baseline.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	COHORT	Num	8	Cohort
3	STRATUM	Num	8	Stratum
4	ARM	Num	8	Treatment Group
5	ACTTRT	Num	8	B2. Which index procedure was initiated?
6	GENDER	Num	8	Gender
7	HISPANIC	Num	8	Ethnicity
8	HTN_YN	Num	8	B1. History of Hypertension
9	DIAB_YN	Num	8	Diabetes
10	DIAB_TX	Num	8	B2a. Type of treatment:
11	HYP_YN	Num	8	B3. Hyperlipidemia
12	CAD_YN	Num	8	B5. Coronary Artery Disease (CAD)
13	PREV_MI	Num	8	B5a. Prior myocardial infarction (MI)
14	PREV_PCI	Num	8	B5b. Prior percutaneous coronary intervention (PCI)
15	PREV_CABG	Num	8	B5c. Prior coronary artery bypass graft surgery (CABG)
16	ANGINA_YN	Num	8	B5d. Angina:
17	CHF_NYHA	Num	8	B6. Heart Failure diagnosed to be New York Heart Association (NYHA) Class 3 or 4:
18	ASA_CLASS	Num	8	B7. American Society of Anesthesia (ASA) Classification:
19	COPD_YN	Num	8	B8. Chronic Obstructive Pulmonary Disease (COPD) requiring medication:
20	TIA_YN	Num	8	B9. History of Transient Ischemic Attack (TIA)
21	STROKE_YN	Num	8	B10. History of Stroke
22	SMOKE_HX	Num	8	Smoking Status
23	SMOKE_PYR	Num	8	B12a. Number of pack-years smoked
24	SMOK_TX_YN	Num	8	B12b. Is the subject currently being treated pharmacologically for smoking?
25	AMB_STAT	Num	8	B13. What is the subject's ambulatory status?
26	LIVE_STAT	Num	8	B15. What was the subject's pre-enrollment living status?
27	BMI	Num	8	Body Mass Index (kg/m2)
28	ALBUMIN	Num	8	C1. Albumin
29	PREV_INFR_IND	Num	8	C1b. Previous infrainguinal reconstruction (>6 months)
30	AGE	Num	8	Age, Years
31	EGFR	Num	8	Estimated GFR (mL/min/1.73 m2)
32	CKDGRADE	Num	8	CKD Grade (including subjects who indicated that Grade 2 or lower)
33	WIFI	Num	8	D3a. Wound grade:
34	WIFISTAGE	Num	8	WIFI Stage
35	PRESS_DP_IND	Num	8	C1a. Systolic pressure (mm Hg)
36	PRESS_PT_IND	Num	8	C2a. Systolic pressure (mm Hg)

Num	Variable	Type	Len	Label
37	PRESS_TOE_IND	Num	8	C3a. Systolic pressure (mm Hg)
38	TBI	Num	8	TB Index
39	ABIMAX	Num	8	Index Leg Maxium ABI
40	VASCU_QOL_SCORE	Num	8	Vascular QoL Overall Score
41	STATIN	Num	8	At least one statin
42	ANTIPLAT	Num	8	At least one antiplatelet drug
43	CLOPIDOGREL	Num	8	At least one clopidogrel
44	WARFARIN	Num	8	At least one warfarin
45	DOAC	Num	8	At least one DOAC
46	ASPIRIN	Num	8	At least one aspirin
47	TICAGRELOR	Num	8	At least one ticagrelor
48	PRASURGEL	Num	8	At least one prasugrel
49	PRESS_DPPT_IND	Num	8	Ankle pressure - maximum of dorsalis pedis or posterior tibial systolic pressure (mm Hg)
50	AMB_STAT3CAT	Num	8	Ambulatory status (3 category)
51	DAPT	Num	8	Dual Antiplatelet Therapy

Data Set Name: demo.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	GENDER	Num	8	B1. Gender:
6	HISPANIC	Num	8	B3. Is subject of Hispanic, Latino, or Spanish origin? (self reported)
7	WHITE	Num	8	B4a. White or Caucasian
8	AFR_AMER	Num	8	B4b. Black or African American
9	RACE_OTH	Num	8	B4f. Other
10	AGE	Num	8	Age, Years

Data Set Name: device.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	LOCATION	Char	4000	A3. Location used
6	LEG	Num	8	A4. In which leg was the device used?
7	TYPE	Num	8	B1. Type of Device
8	TYPE_SP	Char	30	B1a. Specify Other Type
9	NAME	Char	30	B2. Device Name
10	MANUFACT	Char	30	B3. Manufacturer
11	MODEL	Char	30	B4. Model
12	LOT	Char	30	B5. Lot #
13	DEVICE_DAYSRND	Num	8	Days since randomization - A2. Date of Device Use

Data Set Name: endo.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	DAYS_ICU	Num	8	B2. Number of days in Intensive Care Unit (ICU):
6	IMMED_ANGIO	Num	8	B5. Was endovascular procedure performed immediately following the baseline diagnostic angiogram?
7	REVASC_PROC	Num	8	B6. Was a revascularization inflow procedure performed concurrently with the index infrainguinal procedure?
8	START_T	Num	8	B7. Start time (local anesthetic)
9	END_T	Num	8	B8. End time (all operators break scrub)
10	TRANSFUSION	Num	8	B9. Intraprocedural blood transfusion (packed red blood cells):
11	PROTAMINE	Num	8	B10. Did patient receive periprocedural protamine?
12	PRIM_R_L	Num	8	B11a.Right or Left?
13	PRIM_R_A	Num	8	B11b. Retrograde or antegrade?
14	PRIM_VES	Num	8	B11c. Vessel accessed:
15	SEC_ACCESS	Num	8	B12. Was there a second arterial access?
16	SEC_R_L	Num	8	B12a.Right or Left?
17	SEC_R_A	Num	8	B12b. Retrograde or antegrade?
18	SEC_VES	Num	8	B12c. Vessel accessed:
19	TERT_ACCESS	Num	8	B13. Was there a third arterial access?
20	TERT_R_L	Num	8	B13a.Right or Left?
21	TERT_R_A	Num	8	B13b. Retrograde or antegrade?
22	TERT_VES	Num	8	B13c. Vessel accessed:
23	SEGMENTS	Num	8	Number of discrete vascular segments treated:
24	SEG_1	Num	8	C1. Segment 1
25	INIT_STENOSIS_1	Num	8	a1. Please estimate the % stenosis of the most severe lesion in this segment (if occluded please enter 100%).
26	OSTIAL_1	Num	8	a2. Is there an ostial stenosis in this segment of 50% or greater?
27	ENDO_TECH_1	Char	4000	C1b. Please describe endovascular techniques used to treat this segment (select all that apply):
28	DEVICES_1	Num	8	C1c. How many stents or stent-grafts were used to treat this segment?
29	EMBOLIC_1	Num	8	C1d. Was an embolic protection device used?
30	CTO_1_TREAT	Num	8	C1e. Please note the treated length of the lesion (mm)
31	FINAL_STENOSIS_1	Num	8	C1f. Maximum % residual stenosis after treatment for this segment (if occluded please enter 100%)
32	SEG_2	Num	8	C2. Segment 2

Num	Variable	Type	Len	Label
33	INIT_STENOSIS_2	Num	8	a1. Please estimate the % stenosis of the most severe lesion in this segment (if occluded please enter 100%).
34	OSTIAL_2	Num	8	a2. Is there an ostial stenosis in this segment of 50% or greater?
35	ENDO_TECH_2	Char	4000	C2b. Please describe endovascular techniques used to treat this segment (select all that apply):
36	DEVICES_2	Num	8	C2c. How many stents or stent-grafts were used to treat this segment?
37	EMBOLIC_2	Num	8	C2d. Was an embolic protection device used?
38	CTO_2_TREAT	Num	8	C2e. Please note the treated length of the lesion (mm)
39	FINAL_STENOSIS_2	Num	8	C2f. Maximum % residual stenosis after treatment for this segment (if occluded please enter 100%)
40	SEG_3	Num	8	C3. Segment 3
41	INIT_STENOSIS_3	Num	8	a1. Please estimate the % stenosis of the most severe lesion in this segment (if occluded please enter 100%).
42	OSTIAL_3	Num	8	a2. Is there an ostial stenosis in this segment of 50% or greater?
43	ENDO_TECH_3	Char	4000	C3b. Please describe endovascular techniques used to treat this segment (select all that apply):
44	DEVICES_3	Num	8	C3c. How many stents or stent-grafts were used to treat this segment?
45	EMBOLIC_3	Num	8	C3d. Was an embolic protection device used?
46	CTO_3_TREAT	Num	8	C3e. Please note the treated length of the lesion (mm)
47	FINAL_STENOSIS_3	Num	8	C3f. Maximum % residual stenosis after treatment for this segment (if occluded please enter 100%)
48	SEG_4	Num	8	C4. Segment 4
49	INIT_STENOSIS_4	Num	8	a1. Please estimate the % stenosis of the most severe lesion in this segment (if occluded please enter 100%).
50	OSTIAL_4	Num	8	a2. Is there an ostial stenosis in this segment of 50% or greater?
51	ENDO_TECH_4	Char	4000	C4b. Please describe endovascular techniques used to treat this segment (select all that apply):
52	DEVICES_4	Num	8	C4c. How many stents or stent-grafts were used to treat this segment?
53	EMBOLIC_4	Num	8	C4d. Was an embolic protection device used?
54	CTO_4_TREAT	Num	8	C4e. Please note the treated length of the lesion (mm)
55	FINAL_STENOSIS_4	Num	8	C4f. Maximum % residual stenosis after treatment for this segment (if occluded please enter 100%)
56	SEG_5	Num	8	C5. Segment 5
57	INIT_STENOSIS_5	Num	8	a1. Please estimate the % stenosis of the most severe lesion in this segment (if occluded please enter 100%).
58	OSTIAL_5	Num	8	a2. Is there an ostial stenosis in this segment of 50% or greater?
59	ENDO_TECH_5	Char	4000	C5b. Please describe endovascular techniques used to treat this segment (select all that apply):
60	DEVICES_5	Num	8	C5c. How many stents or stent-grafts were used to treat this segment?
61	EMBOLIC_5	Num	8	C5d. Was an embolic protection device used?
62	CTO_5_TREAT	Num	8	C5e. Please note the treated length of the lesion (mm)
63	FINAL_STENOSIS_5	Num	8	C5f. Maximum % residual stenosis after treatment for this segment (if occluded please enter 100%)

Num	Variable	Type	Len	Label
64	SEG_6	Num	8	C6. Segment 6
65	INIT_STENOSIS_6	Num	8	a1. Please estimate the % stenosis of the most severe lesion in this segment (if occluded please enter 100%).
66	OSTIAL_6	Num	8	a2. Is there an ostial stenosis in this segment of 50% or greater?
67	ENDO_TECH_6	Char	4000	C6b. Please describe endovascular techniques used to treat this segment (select all that apply):
68	DEVICES_6	Num	8	C6c. How many stents or stent-grafts were used to treat this segment?
69	EMBOLIC_6	Num	8	C6d. Was an embolic protection device used?
70	CTO_6_TREAT	Num	8	C6e. Please note the treated length of the lesion (mm)
71	FINAL_STENOSIS_6	Num	8	C6f. Maximum % residual stenosis after treatment for this segment (if occluded please enter 100%)
72	SEG_7	Num	8	C7. Segment 7
73	INIT_STENOSIS_7	Num	8	a1. Please estimate the % stenosis of the most severe lesion in this segment (if occluded please enter 100%).
74	OSTIAL_7	Num	8	a2. Is there an ostial stenosis in this segment of 50% or greater?
75	ENDO_TECH_7	Char	4000	C7b. Please describe endovascular techniques used to treat this segment (select all that apply):
76	DEVICES_7	Num	8	C7c. How many stents or stent-grafts were used to treat this segment?
77	EMBOLIC_7	Num	8	C7d. Was an embolic protection device used?
78	CTO_7_TREAT	Num	8	C7e. Please note the treated length of the lesion (mm)
79	FINAL_STENOSIS_7	Num	8	C7f. Maximum % residual stenosis after treatment for this segment (if occluded please enter 100%)
80	SEG_8	Num	8	C8. Segment 8
81	INIT_STENOSIS_8	Num	8	a1. Please estimate the % stenosis of the most severe lesion in this segment (if occluded please enter 100%).
82	OSTIAL_8	Num	8	a2. Is there an ostial stenosis in this segment of 50% or greater?
83	ENDO_TECH_8	Char	4000	C8b. Please describe endovascular techniques used to treat this segment (select all that apply):
84	DEVICES_8	Num	8	C8c. How many stents or stent-grafts were used to treat this segment?
85	EMBOLIC_8	Num	8	C8d. Was an embolic protection device used?
86	CTO_8_TREAT	Num	8	C8e. Please note the treated length of the lesion (mm)
87	FINAL_STENOSIS_8	Num	8	C8f. Maximum % residual stenosis after treatment for this segment (if occluded please enter 100%)
88	THROM_1	Num	8	D1. Arterial thrombosis
89	THROM_1_TREAT	Num	8	D1a. Treatment
90	EMBOL_1	Num	8	D2. Arterial embolization
91	EMBOL_1_TREAT	Num	8	D2a. Treatment
92	FLOW_LIM_1	Num	8	D3. Flow-limiting dissection
93	FLOW_1_TREAT	Num	8	D3a. Treatment
94	PERFORAT_1	Num	8	D4. Perforation or rupture
95	PERF_1_TREAT	Num	8	D4a. Treatment

Num	Variable	Type	Len	Label
96	SUCCESS_1	Num	8	D5. Was the procedure a technical success (i.e., successful traversal and treatment of intended targets, with <50% residual stenosis in superficial femoral artery, popliteal and at least one tibial artery to the foot)?
97	UNSUCCESS_1_REAS	Num	8	D5a. If technical success is not achieved, please list reason:
98	OTHER_REAS	Char	500	D5a1. If "other," specify:
99	OPEN_PROC	Num	8	D5b. If initial procedure was not a technical success, was an open surgical procedure performed?
100	CONTRAST	Num	8	E1. Intravenous contrast volume total (mL)
101	CO2_CONTRAST	Num	8	E2. Was carbon dioxide used as a contrast agent?
102	DOSE_AREA_PROD	Num	8	E3. Dose Area Product (Gy cm²)
103	CLOSURE	Num	8	E4. Closure device used
104	SHEATH	Num	8	E5. Largest access sheath size (F)
105	IPSIL_CFA	Num	8	B14. Was an intervention performed on the ipsilateral common femoral artery?
106	SURG_END	Num	8	B14a. Was it surgical (endarterectomy)?
107	PATCH	Num	8	B14a2. Specify Patch
108	ENDART	Num	8	B14a3. Did the endarterectomy extend into the proximal superficial femoral artery?
109	CONCUR	Num	8	B14a4. Was it done concurrently with the index revascularization?
110	ENDOVASC	Num	8	B14b. Was it endovascular?
111	ENDOVASC_SP	Num	8	B14ba. If Yes, please describe endovascular techniques used to treat this segment
112	IPSIL_DFA	Num	8	B15. Was an intervention performed on the ipsilateral deep femoral artery?
113	SURG_END_DFA	Num	8	B15a. Was it surgical (endarterectomy)?
114	PATCH_DFA	Num	8	B15a2. Specify Patch
115	CONCUR_DFA	Num	8	B15a3. Was it done concurrently with the index revascularization?
116	ENDOVASC_DFA	Num	8	B15b. Was it endovascular?
117	ENDOVASCU_DFA_SP	Num	8	B15b1. If Yes, please describe endovascular techniques used to treat this segment
118	PROC_DAYSRND	Num	8	Days since randomization - B1. Date of Procedure
119	SURG_END_DAYSRND	Num	8	Days since randomization - B14a1. Date
120	SURG_END_DFA_DAYSRND	Num	8	Days since randomization - B15a1. Date

Data Set Name: endocfa.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	ENDOVASC_SP	Char	4000	B2a1. If Yes, please describe endovascular techniques used to treat this segment
6	ENDOVASCU_DFA_SP	Char	4000	B3a1. If Yes, please describe endovascular techniques used to treat this segment

Data Set Name: eq5d.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	WHO_COMP	Num	8	A2. Who filled out this quality of life questionnaire?
6	UNC_DEAD_YN	Num	8	A2a. Is the subject unconscious or dead?
7	MOBILITY	Num	8	B1. Mobility
8	SELF_CARE	Num	8	B2. Self-Care
9	US_ACT	Num	8	B3. Usual Activities (e.g. work, study, housework, family or leisure activities)
10	PAIN	Num	8	B4. Pain/ Discomfort
11	ANX_DEP	Num	8	B5. Anxiety/Depression
12	HEALTH_STATE	Num	8	C1. Your own health state today (0 being Worst Imaginable Health State and 100 being Best Imaginable Health State)
13	MODE_ADMIN	Num	8	A2. Mode of administration:
14	INTERPRET	Num	8	A3. Was an interpreter used?
15	COMP_DAYSRND	Num	8	Days since randomization - A5. Completion Date

Data Set Name: excl.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	TASC_IIA	Num	8	B1. Disease limited to the femoropopliteal segment with TASC II A pattern.
6	FA_DISEASE	Num	8	B2. Presence of severe (> 50% stenosis) ipsilateral common femoral artery disease.
7	ANEURYSM	Num	8	B3. Presence of a popliteal aneurysm (>2 cm) in the index limb.
8	LIFE_EXPECT	Num	8	B4. Life expectancy of less than 2 years due to reasons other than Peripheral Artery Disease (PAD).
9	EXCESS_RISK	Num	8	B5. Deemed excessive risk for surgical bypass.
10	PLAN_AMP	Num	8	B6. Planned above ankle amputation on ipsilateral limb within 4 weeks of index procedure.
11	HYPR_COAG	Num	8	B7. Known anti-phospholipid antibodies or lupus anticoagulant, known Protein C deficiency, Protein S deficiency, or Antithrombin III deficiency if treated or advised to be treated with long-term anticoagulation as a result of this diagnosis.
12	NA_OCC_DIS	Num	8	B8. Non-atherosclerotic occlusive disease (e.g. trauma, vasculitis, Buerger's disease) or acute limb-threatening ischemia (defined as tissue loss or ischemic rest pain of less than 14 days duration).
13	PRIOR_STENT	Num	8	B9. Any prior index limb infrainguinal stenting or stent grafting associated with significant restenosis.
14	ENDO_PROC	Num	8	B10a. Infrainguinal balloon angioplasty, atherectomy, stent or stentgraft;
15	FEM_ENDART	Num	8	B10b. Common, superficial, or deep femoral endarterectomy;
16	INFR_BYPASS	Num	8	B10c. Infrainguinal bypass with either venous or prosthetic conduit;
17	OPEN_SURG	Num	8	B10d. Open surgical inflow procedure (aortofemoral, axillofemoral, iliofemoral, thoracofemoral, or femorofemoral bypass);
18	CURR_TX	Num	8	B11. Current immune-suppressive medication, chemotherapy or radiation therapy.
19	CONTRAST	Num	8	B12. Absolute contraindication to iodinated contrast.
20	ALLERGY	Num	8	B13. Known allergy to stainless steel or nitinol.
21	PREGNANCY	Num	8	B14. Pregnancy or lactation.
22	INVEST_DRUG	Num	8	B15. Administration of an investigational drug for Peripheral Arterial Disease (PAD) within 30 days of randomization.
23	CLIN_TRIAL	Num	8	B16. Participation in a clinical trial (except observational studies) within the previous 30 days.
24	PRIOR_BEST	Num	8	B17. Prior enrollment or randomization into BEST-CLI.
25	EXCL_YN	Num	8	Any Exclusion Criteria Met:
26	AV_BD_ALTI	Num	8	B5. Active vasculitis, Buerger's disease or acute limb-threatening ischemia.

Data Set Name: extra.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	ENDO	Char	1	Trigger additional ENDO form?
6	OPEN	Char	1	Trigger additional OPEN form?

Data Set Name: fmri1.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	BYPASS_GRAFT	Num	8	B1. New bypass graft placement
6	JUMP_GRAFT	Num	8	B2. Jump/interposition graft revision
7	OS_THROMB	Num	8	B3. Open Surgical Thrombectomy
8	MECH_THROMB	Num	8	B4. Mechanical Thrombosis
9	SP_ANGIO	Num	8	B5. Surgical Patch Angioplasty
10	BALLOON	Num	8	B6. Balloon Angioplasty
11	ATHERECTOMY	Num	8	B7. Atherectomy
12	LASER	Num	8	B8. Laser Treatment
13	STENT	Num	8	B9. Stent Placement
14	STENT_GRAFT	Num	8	B10. Stent-graft Placement
15	PHARMA_THROMB	Num	8	B11. Pharmacologic Thrombolysis
16	MAJOR_YN	Num	8	C1. Does this event meet the study definition of a Major Re-Intervention?

Data Set Name: fmri2.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	BYPASS_GRAFT	Num	8	B1. New bypass graft placement
6	JUMP_GRAFT	Num	8	B2. Jump/interposition graft revision
7	OS_THROMB	Num	8	B3. Open Surgical Thrombectomy
8	MECH_THROMB	Num	8	B4. Mechanical Thrombosis
9	SP_ANGIO	Num	8	B5. Surgical Patch Angioplasty
10	BALLOON	Num	8	B6. Balloon Angioplasty
11	ATHERECTOMY	Num	8	B7. Atherectomy
12	LASER	Num	8	B8. Laser Treatment
13	STENT	Num	8	B9. Stent Placement
14	STENT_GRAFT	Num	8	B10. Stent-graft Placement
15	PHARMA_THROMB	Num	8	B11. Pharmacologic Thrombolysis
16	MAJOR_YN	Num	8	C1. Does this event meet the study definition of a Major Re-Intervention?

Data Set Name: fmri3.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	BYPASS_GRAFT	Num	8	B1. New bypass graft placement
6	JUMP_GRAFT	Num	8	B2. Jump/interposition graft revision
7	OS_THROMB	Num	8	B3. Open Surgical Thrombectomy
8	MECH_THROMB	Num	8	B4. Mechanical Thrombosis
9	SP_ANGIO	Num	8	B5. Surgical Patch Angioplasty
10	BALLOON	Num	8	B6. Balloon Angioplasty
11	ATHERECTOMY	Num	8	B7. Atherectomy
12	LASER	Num	8	B8. Laser Treatment
13	STENT	Num	8	B9. Stent Placement
14	STENT_GRAFT	Num	8	B10. Stent-graft Placement
15	PHARMA_THROMB	Num	8	B11. Pharmacologic Thrombolysis
16	MAJOR_YN	Num	8	C1. Does this event meet the study definition of a Major Re-Intervention?

Data Set Name: fmri_o.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	CEC_EVENT	Num	8	A3. Unique Identifier of Event Under Review
6	FULL_COMM	Num	8	A4. Is this a full committee review?
7	BYPASS_GRAFT	Num	8	B1. New bypass graft placement
8	JUMP_GRAFT	Num	8	B2. Jump/interposition graft revision
9	OS_THROMB	Num	8	B3. Open Surgical Thrombectomy
10	MECH_THROMB	Num	8	B4. Mechanical Thrombosis
11	SP_ANGIO	Num	8	B5. Surgical Patch Angioplasty
12	BALLOON	Num	8	B6. Balloon Angioplasty
13	ATHERECTOMY	Num	8	B7. Atherectomy
14	LASER	Num	8	B8. Laser Treatment
15	STENT	Num	8	B9. Stent Placement
16	STENT_GRAFT	Num	8	B10. Stent-graft Placement
17	PHARMA_THROMB	Num	8	B11. Pharmacologic Thrombolysis
18	MAJOR_YN	Num	8	C1. Does this event meet the study definition of a Major Re-Intervention?
19	REINTER_DAYSRND	Num	8	Days since randomization - A2. Date of Re-Intervention Under Review

Data Set Name: health_util.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	HOSP	Num	8	B1. Was subject hospitalized?
6	HOSP_NUM	Num	8	B1a. IF YES, how many times?
7	ED_VISIT	Num	8	B2. Did the subject visit an emergency department (that did not result in hospitalization)?
8	ED_VISIT_NUM	Num	8	B2a. IF YES, how many times?
9	PROC_TEST	Num	8	B3. Did the subject have an outpatient procedure or diagnostic test (unrelated to a hospitalization or ER visit)?
10	PROC_TEST_NUM	Num	8	B3a. IF YES, how many times?
11	OUTPAT_VISIT	Num	8	B4. Did the subject have an outpatient office visit?
12	OUTPAT_VISIT_NUM	Num	8	B4a. IF YES, how many times?
13	OUT_REHAB	Num	8	B5. Did the subject use any outpatient rehabilitation services?
14	OUTPAT_REHAB_HOUR	Num	8	B5a. IF YES, approximate number of hours?
15	INPAT_REHAB	Num	8	B6. Did the subject use any long-term care or inpatient rehabilitation/skilled nursing care services?
16	INPAT_REHAB_DAYS	Num	8	B6a. IF YES, number of days as an inpatient?
17	WORK_MISSED	Num	8	B7. How many hours of work were missed by the subject for all outpatient ED visits, procedures, tests, or physician visits since the last study visit?
18	INFORMAL_CARE	Num	8	B8. Did the subject receive any informal care from family or friends?
19	INFORM_CARE_HRS	Num	8	B8a. IF YES, approximate number of hours?
20	EMPLOY_STAT	Num	8	B7. What is the subject's employment status?

Data Set Name: hem_assess.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	R_BRACH_PR	Num	8	B1. Was right brachial blood pressure (BP) measured?
6	SBP_R	Num	8	B1a. Right Systolic BP (mm Hg)
7	DBP_R	Num	8	B1b. Right Diastolic BP (mm Hg)
8	L_BRACH_PR	Num	8	B2. Was left brachial blood pressure (BP) measured?
9	SBP_L	Num	8	B2a. Left Systolic BP (mm Hg)
10	DBP_L	Num	8	B2b. Left Diastolic BP (mm Hg)
11	DP_IND	Num	8	C1. Dorsalis Pedis
12	PRESS_DP_IND	Num	8	C1a. Systolic pressure (mm Hg)
13	PT_IND	Num	8	C2. Posterior Tibial
14	PRESS_PT_IND	Num	8	C2a. Systolic pressure (mm Hg)
15	TOE_IND	Num	8	C3. Great Toe
16	PRESS_TOE_IND	Num	8	C3a. Systolic pressure (mm Hg)
17	TCPO2_YN_IND	Num	8	C4. Were TcPO2 measurements taken?
18	CHEST_IND	Num	8	C4a. Reference Pressure (at chest wall) (mm Hg)
19	TMA_IND	Num	8	C4b. Transmetatarsal Level Pressure (mm Hg)
20	PVR_IND	Num	8	C5. Pulse-volume recording (PVR) at Transmetatarsal Level
21	DOPPLER_IND	Num	8	C6. Were doppler waveforms obtained?
22	FEM_DOP_IND	Num	8	C6a. Femoral artery
23	DP_DOP_IND	Num	8	C6b. Dorsalis pedis artery
24	PT_DOP_IND	Num	8	C6c. Posterior tibial artery
25	DP_NIL	Num	8	D1. Dorsalis Pedis
26	PRESS_DP_NIL	Num	8	D1a. Systolic pressure (mm Hg)
27	PT_NIL	Num	8	D2. Posterior Tibial
28	PRESS_PT_NIL	Num	8	D2a. Systolic pressure (mm Hg)
29	TOE_NIL	Num	8	D3. Great Toe
30	PRESS_TOE_NIL	Num	8	D3a. Systolic pressure (mm Hg)
31	TCPO2_YN_NIL	Num	8	D4. Were TcPO2 measurements taken?
32	CHEST_NIL	Num	8	D4a. Reference Pressure (at chest wall) (mm Hg)
33	TMA_NIL	Num	8	D4b. Transmetatarsal Level Pressure (mm Hg)
34	PVR_NIL	Num	8	D5. Pulse-volume recording (PVR) at Transmetatarsal Level
35	DOPPLER_NIL	Num	8	D6. Were doppler waveforms obtained?
36	FEM_DOP_NIL	Num	8	D6a. Femoral artery

Num	Variable	Type	Len	Label
37	DP_DOP_NIL	Num	8	D6b. Dorsalis pedis artery
38	PT_DOP_NIL	Num	8	D6c. Posterior tibial artery
39	ART_DUPLEX	Num	8	E1. Was arterial duplex performed?
40	LOW_PSV	Num	8	E3. Lowest Peak Systolic Velocity (PSV) in bypass graft (cm/sec)
41	HIGH_PSV	Num	8	E4. Highest Peak Systolic Velocity (PSV) in bypass graft (cm/sec)
42	PROX_PSV	Num	8	E5. Velocity immediately proximal to highest PSV (cm/sec)
43	ASSESS_DAYSRND	Num	8	Days since randomization - A2. Date of Assessment
44	DUPLEX_DAYSRND	Num	8	Days since randomization - E2. Date of duplex

Data Set Name: hosp_ed.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	ED_ADMIN	Num	8	B1. Was the subject seen in:
6	HOSP_ICU	Num	8	B4. During this hospitalization was the subject in the ICU?
7	ICU_IN_TIME	Num	8	B4b. Time admitted to ICU
8	ICU_OUT_TIME	Num	8	B4d. Time discharged from ICU
9	PRIM_DIAG	Num	8	C1. Primary Diagnosis (select one)
10	SEC_DIAG	Num	8	D1. Were there any secondary diagnoses?
11	MI_ACS	Num	8	D1a. Acute MI/acute coronary syndrome
12	CHF_NYHA	Num	8	D1b. CHF NYHA class III or IV
13	COPD	Num	8	D1c. COPD
14	STROKE_TIA	Num	8	D1d. Stroke/TIA
15	ACUTE_KIDNEY	Num	8	D1e. Acute kidney injury
16	DVT_PE	Num	8	D1f. Deep venous thrombosis and/or pulmonary embolism
17	SEPSIS	Num	8	D1g. Sepsis
18	SECOND_OTHER	Num	8	D1h. Other
19	DIALYSIS	Num	8	E1. Dialysis
20	TRACH	Num	8	E2. Tracheostomy
21	GI_ENDO	Num	8	E3. Gastrointestinal endoscopy
22	GI_ENDO_NUM	Num	8	E3a. How many?
23	CARD_CATH	Num	8	E4. Cardiac catheterization
24	CARD_CATH_NUM	Num	8	E4a. How many?
25	CT_ANGIO	Num	8	E5. CT scan (including angiography)
26	CT_ANGIO_NUM	Num	8	E5a. How many?
27	MRI_ANGIO	Num	8	E6. MRI (including angiography)
28	MRI_ANGIO_NUM	Num	8	E6a. How many?
29	ULTRASOUND	Num	8	E7. Ultrasound (including venous or arterial ultrasound studies)
30	ULTRASOUND_NUM	Num	8	E7a. How many?
31	ECHO	Num	8	E8. Echocardiogram
32	ECHO_NUM	Num	8	E8a. How many?
33	CARD_STRESS	Num	8	E9. Cardiac stress test
34	CARD_STRESS_NUM	Num	8	E9a. How many?
35	PHYS_THER	Num	8	E10. Physical therapy
36	DISCHAR_DISP	Num	8	F1. What was the patient’s discharge disposition?

Num	Variable	Type	Len	Label
37	STUDY_SITE	Num	8	B1a. Did this hospitalization/ED encounter occur at the BEST study site?
38	ADMIN_DAYSRND	Num	8	Days since randomization - B2. Date seen in ED/Date of Admission
39	DISCHARGE_DAYSRND	Num	8	Days since randomization - B3. Date of Discharge
40	ICU_IN_DAYSRND	Num	8	Days since randomization - B4a. Date admitted to ICU
41	ICU_OUT_DAYSRND	Num	8	Days since randomization - B4c. Date discharged from ICU
42	DIAL_START_DAYSRND	Num	8	Days since randomization - E1a. Start Date
43	DIAL_STOP_DAYSRND	Num	8	Days since randomization - E1b. Stop Date

Data Set Name: icf.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	ICF_OBT	Num	8	B1. Was written Informed Consent obtained?
6	ICF_DAYSRND	Num	8	Days since randomization - B2. Date Informed Consent signed

Data Set Name: imr.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	BYPASS_GRAFT	Num	8	B1. New bypass graft placement
6	JUMP_GRAFT	Num	8	B2. Jump/interposition graft revision
7	OS_THROMB	Num	8	B3. Open Surgical Thrombectomy
8	MECH_THROMB	Num	8	B4. Mechanical Thrombolysis
9	SP_ANGIO	Num	8	B5. Surgical Patch Angioplasty
10	BALLOON	Num	8	B6. Balloon Angioplasty
11	ATHERECTOMY	Num	8	B7. Atherectomy
12	LASER	Num	8	B8. Laser Treatment
13	STENT	Num	8	B9. Stent Placement
14	STENT_GRAFT	Num	8	B10. Stent-graft Placement
15	PHARMA_THROMB	Num	8	B11. Pharmacologic Thrombolysis
16	MAJOR_YN	Num	8	C1. Does this event meet the study definition of a Major Re-Intervention?
17	REINT_DAYSRND	Num	8	Days since randomization - A2. Date of Re-Intervention Under Review

Data Set Name: incl.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	MF_35_YN	Num	8	B1. Male or female, age 35 years or older.
6	PAD_YN	Num	8	B2. Atherosclerotic, infrainguinal Peripheral Artery Disease (PAD)
7	CLI_YN	Num	8	B3. Critical Limb Ischemia (CLI), defined as arterial insufficiency with gangrene, non-healing ischemic ulcer, or rest pain consistent with Rutherford categories 4, 5 or 6.
8	BOTH_YN	Num	8	B4. Candidate for both open and endovascular infrainguinal revascularization as judged by the treating investigator.
9	INFLOW_YN	Num	8	B5. Adequate aortoiliac inflow
10	TARGET_YN	Num	8	B6. Adequate popliteal, tibial or pedal revascularization target defined as an infrainguinal arterial segment distal to the area of stenosis/occlusion which can support a distal anastomosis of a surgical bypass.
11	WILLING_YN	Num	8	B7. Willingness to comply with protocol, attend follow-up appointments, complete all study assessments, and provide written informed consent.
12	INCL_YN	Num	8	All Inclusion Criteria Met:
13	MF_18_YN	Num	8	B1. Male or female, age 18 years or older.

Data Set Name: index_sum.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	RAND_ASSIGN	Num	8	B1. Which procedure was the subject randomized to?
3	ASSIGNED	Num	8	B2. Which index procedure was initiated?
4	WHO_DECIDE	Num	8	B2a.Who made the decision not to initiate the randomized procedure?
5	ASSIGN_REAS	Num	8	B2b. Why wasn't the randomized procedure initiated?
6	REINT_ADJ_YN	Num	8	First Major Re-Intervention for adjudication?
7	REINT_ADJ1	Char	1	Trigger Adjudicator Form 1 (Tsai)
8	REINT_ADJ2	Char	1	Trigger Adjudicator Form 2 (Sheahan)
9	REINT_ADJ3	Char	1	Trigger Adjudicator Form 3 (Ouriel)
10	PROC_DAYSRND	Num	8	Days since randomization - Date of Index Procedure
11	REINT_ADJ_DAYSRND	Num	8	Days since randomization - Date of Re-Intervention

Data Set Name: labs.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	CREAT_YN	Num	8	B1. Was Creatinine test performed?
6	CREAT_RES	Num	8	B3. Creatinine Result
7	CREAT_UN	Num	8	B3a. Creatinine Unit
8	ALBUMIN	Num	8	C1. Albumin
9	HEMOGLOBIN	Num	8	C2. Hemoglobin A1c
10	LIPID_YN	Num	8	C3. Was a lipid profile obtained?
11	TOTAL_CHOL	Num	8	C3b1. Total Cholesterol
12	LDL	Num	8	C3b2. Low density lipoprotein (LDL)
13	HDL	Num	8	C3b3. High density lipoprotein (HDL)
14	TRIGLYCERIDES	Num	8	C3b4. Triglycerides
15	ALBUMIN_YN	Num	8	C1. Was an Albumin result obtained?
16	HEMOG_YN	Num	8	C2. Was a Hemoglobin A1c result obtained?
17	CREAT_DAYSRND	Num	8	Days since randomization - B2. Blood draw date
18	ALBUMIN_DAYSRND	Num	8	Days since randomization - C1b. Blood draw date
19	HEMOG_DAYSRND	Num	8	Days since randomization - C2b. Blood draw date
20	LIPID_DAYSRND	Num	8	Days since randomization - C3a. Blood draw date

Data Set Name: med.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	VISIT	Num	8	A2. Visit:
6	NAME	Char	30	B1. Medication Name
7	DOSAGE	Num	8	B2. Total Daily Dose
8	DOS_UN	Char	10	B3. Dosage Units
9	CODE	Char	1500	CODE
10	DRUG_NAME	Char	1500	DRUG_NAME
11	CODE4	Char	1500	CODE4
12	TEXT4	Char	1500	TEXT4
13	CODE3	Char	1500	CODE3
14	TEXT3	Char	1500	TEXT3
15	CODE2	Char	1500	CODE2
16	TEXT2	Char	1500	TEXT2
17	CODE1	Char	1500	CODE1
18	TEXT1	Char	1500	TEXT1

Data Set Name: med_hist.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	HTN_YN	Num	8	B1. History of Hypertension
6	DIAB_YN	Num	8	B2. Diabetes
7	DIAB_TX	Num	8	B2a. Type of treatment:
8	HYP_YN	Num	8	B3. Hyperlipidemia
9	HYP_LIP_YN	Num	8	B3a. Is the subject currently being treated for hyperlipidemia?
10	STATIN	Num	8	B4. Is the subject on a statin?
11	STATIN_SPEC	Char	4000	B4a. If other, specify:
12	CAD_YN	Num	8	B5. Coronary Artery Disease (CAD)
13	PREV_MI	Num	8	B5a. Prior myocardial infarction (MI)
14	PREV_PCI	Num	8	B5b. Prior percutaneous coronary intervention (PCI)
15	PREV_CABG	Num	8	B5c. Prior coronary artery bypass graft surgery (CABG)
16	ANGINA_YN	Num	8	B5d. Angina:
17	CHF_NYHA	Num	8	B6. Heart Failure diagnosed to be New York Heart Association (NYHA) Class 3 or 4:
18	ASA_CLASS	Num	8	B7. American Society of Anesthesia (ASA) Classification:
19	COPD_YN	Num	8	B8. Chronic Obstructive Pulmonary Disease (COPD) requiring medication:
20	HOME_O2	Num	8	B8a. Is the subject on home oxygen?
21	TIA_YN	Num	8	B9. History of Transient Ischemic Attack (TIA)
22	STROKE_YN	Num	8	B10. History of Stroke
23	CKD_YN	Num	8	B11. Chronic kidney disease (CKD):
24	CKD_GRADE	Num	8	B11a. CKD Grade:
25	SMOKE_HX	Num	8	B12. Does the subject have a history of smoking?
26	SMOKE_PYR	Num	8	B12a. Number of pack-years smoked
27	SMOK_TX_YN	Num	8	B12b. Is the subject currently being treated pharmacologically for smoking?
28	AMB_STAT	Num	8	B13. What is the subject's ambulatory status?
29	EXERCISE	Num	8	B14. Please describe the subject's typical weekly exercise habits.
30	LIVE_STAT	Num	8	B15. What was the subject's pre-enrollment living status?

Data Set Name: medc.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	REPORT	Num	8	Are there any medications to report at this visit?
6	MEDS_NO	Num	8	If yes, how many?

Data Set Name: mi_rev1.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	STUDY_DEF	Num	8	B1. Does the event meet the study definition of a myocardial infarction?

Data Set Name: mi_rev2.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	STUDY_DEF	Num	8	B1. Does the event meet the study definition of a myocardial infarction?

Data Set Name: mi_rev3.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	CEC_EVENT	Num	8	A3. Unique Identifier of Event Under Review
6	FULL_COMM	Num	8	A4. Is this a full committee review?
7	STUDY_DEF	Num	8	B1. Does the event meet the study definition of a myocardial infarction?
8	EVENT_DAYSRND	Num	8	Days since randomization - A2. Date of Event Under Review

Data Set Name: mi_rev_3.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	STUDY_DEF	Num	8	B1. Does the event meet the study definition of a myocardial infarction?

Data Set Name: open_surg.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	DAYS_ICU	Num	8	B2. Number of days in Intensive Care Unit (ICU):
6	SKIN_PREP	Char	4000	B4. Skin preparation
7	INCISION_T	Num	8	B5. Time of incision:
8	CLOSURE_T	Num	8	B6. Time closure completed:
9	BLODD_LOSS	Num	8	B7. Estimated blood loss (cc):
10	TRANSFUSION	Num	8	B8. Intraprocedural blood transfusion (packed red blood cells):
11	PREOP_AB	Num	8	B9. Did the subject receive perioperative antibiotics?
12	PREOP_AB_SP	Num	8	B9a. If Yes, which antibiotic:
13	PROTAMINE	Num	8	B10. Did subject receive intraoperative protamine?
14	CLO_PRA_TIC	Num	8	B11. If subject on clopidogrel, prasugrel, or ticagrelor prior to surgery, was it stopped 3 or more days prior to anticipated surgical procedure?
15	SECOND_SURG	Num	8	B12. Did a second attending surgeon spend > 50% of time assisting in case?
16	FEM_ENDART	Num	8	B13. Was a femoral endarterectomy performed?
17	PATCH	Num	8	B13a. If yes, specify patch used:
18	GRAFT_DONOR	Num	8	B14. Bypass graft origin site
19	GRAFT_RECP	Num	8	B15. Bypass graft distal target site
20	GREAT_SAPH	Num	8	B16a. Was single segment great saphenous vein used as conduit?
21	VEIN_HARV	Num	8	B16a1. If Yes, please describe harvesting technique:
22	COND_MANAG	Num	8	B16a2. If Yes, please list conduit management technique:
23	LEG	Num	8	B16a3. If Yes, list leg from which vein was harvested:
24	AUTOG_YN	Num	8	B16b. Was alternative autogenous vein used?
25	CEPH_VEIN	Num	8	B16b1. Cephalic vein
26	BAS_VEIN	Num	8	B16b2. Basilic vein
27	SS_VEIN	Num	8	B16b3. Short saphenous vein
28	VN_OTHER	Num	8	B16b4. Other
29	VEIN_SEG_NO	Num	8	B16b5. How many vein segments were used?
30	PROSTH_COND_YN	Num	8	B16c. Was a non-autogenous conduit used?
31	PROSTH_VEIN	Num	8	B16c1. If yes, specify:
32	END_END	Num	8	B16d. Was a prosthetic-vein (end-end anastomosis) bypass used?
33	NON_CONTIG	Num	8	B16e. Was a sequential graft (end-side anastomosis, or non-contiguous anastomoses) bypass used?
34	DIST_VEIN	Num	8	B16f. Was a distal vein cuff or patch used?

Num	Variable	Type	Len	Label
35	DIAM_VEIN	Num	8	B16g. Please measure and record the intraoperative minimal diameter of the vein used.
36	COMP_STUDY	Num	8	B17. Was a completion study performed?
37	IMMED_REV	Num	8	B17a. Did the completion study lead to immediate revision of graft?
38	CONCUR_AMP	Num	8	B18. Was index leg wound debridement or toe/foot amputation performed concurrent with index procedure?
39	STAGED_AMP	Num	8	B19. Is staged index leg wound debridement or toe/foot amputation expected?
40	DRAIN_YN	Num	8	B20. Was surgical drain left in place?
41	SKIN_CLOS	Num	8	B21. How was the skin closure performed?
42	END_AORT_INT	Num	8	B22. Was an endovascular aortoiliac intervention performed on the index leg concurrently with the surgical bypass?
43	TECH_SUC	Num	8	B23. Was procedure considered a technical success (i.e. patent bypass graft and a pulse and/or improved doppler signal at the ankle or foot detected at the end of the procedure)?
44	ENDO_PROC	Num	8	B23a. If initial procedure was not a technical success, was an infrainguinal endovascular procedure performed?
45	COMP_YN	Num	8	B24. Did any non-surgical complication occur during the operation?
46	IPSIL_CFA	Num	8	B13. Was an intervention performed on the ipsilateral common femoral artery?
47	SURG_END_CFA	Num	8	B13a. Was it surgical (endarterectomy)?
48	PATCH_CFA	Num	8	B13a2. Specify Patch
49	CONCUR_CFA	Num	8	B13a3. Was it done concurrently with the index revascularization?
50	IPSIL_END_CFA	Num	8	B13a4. Did the endarterectomy extend into the proximal superficial femoral artery?
51	ENDOVASC	Num	8	B13b. Was it endovascular?
52	ENDOVASC_SP	Num	8	B13b1. If Yes, please describe endovascular techniques used to treat this segment
53	IPSIL_DFA	Num	8	B14. Was an intervention performed on the ipsilateral deep femoral artery?
54	SURG_END_DFA	Num	8	B14a. Was it surgical (endarterectomy)?
55	PATCH_DFA	Num	8	B14a2. Specify patch
56	CONCUR_DFA	Num	8	B14a3. Was it done concurrently with the index revascularization?
57	ENDOVASC_YN	Num	8	B14b. Was it endovascular?
58	ENDOVASC_DFA_SP	Num	8	B14b1. If Yes, please describe endovascular techniques used to treat this segment
59	PROC_DAYSRND	Num	8	Days since randomization - B1. Date of Procedure
60	SURG_END_CFA_DAYSRND	Num	8	Days since randomization - B13a1. Date
61	SURG_END_DFA_DAYSRND	Num	8	Days since randomization - B14a1. Date

Data Set Name: pain.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	WHO_COMP	Num	8	A2. Who filled out this quality of life questionnaire?
6	PAIN_NOW	Num	8	B1. On a scale of 0 to 10, with 0 being no pain at all and 10 being the worst pain imaginable, how would you rate your pain RIGHT NOW.
7	PAIN_USUAL	Num	8	B2. On the same scale, how would you rate your USUAL level of pain during the last week.
8	PAIN_BEST	Num	8	B3. On the same scale, how would you rate your BEST level of pain during the last week.
9	PAIN_WORST	Num	8	B4. On the same scale, how would you rate your WORST level of pain during the last week.
10	MODE_ADMIN	Num	8	A2. Mode of administration:
11	INTERPRET	Num	8	A3. Was an interpreter used?
12	COMP_DAYSRND	Num	8	Days since randomization - A5. Completion Date

Data Set Name: pnilif.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	PROC	Num	8	B1. At any point after BEST-CLI randomization, has the patient had an above ankle amputation, or an open or endovascular infrainguinal revascularization procedure on the non-index leg?
6	AB_AMP	Num	8	B1a. Did the subject have an above ankle amputation?
7	BPGRAFT	Num	8	B1b. Did the subject have a bypass graft placement?
8	ENDOREV	Num	8	B1c. Did the subject have an endovascular revascularization?
9	BANGIO	Num	8	B1c2. Did the subject have a balloon angioplasty?
10	ATHER	Num	8	B1c3. Did the subject have an atherectomy?
11	STENT	Num	8	B1c4. Did the subject have a stent or stent graft placement?
12	FC_DAYSRND	Num	8	Days since randomization - A2. Date form completed
13	AMP_DAYSRND	Num	8	Days since randomization - B1a1. Date of amputation
14	GRAFT_DAYSRND	Num	8	Days since randomization - B1b1. Date of first procedure
15	REV_DAYSRND	Num	8	Days since randomization - B1c1. Date of first Intervention
16	ANG_DAYSRND	Num	8	Days since randomization - B1c2a. Date of first angioplasty
17	ATHER_DAYSRND	Num	8	Days since randomization - B1c3a. Date of first atherectomy
18	STENT_DAYSRND	Num	8	Days since randomization - B1c4a Date of first stent or stent graft placement

Data Set Name: proc_indexvst.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	GREAT_SAPH	Num	8	B16a. Was single segment great saphenous vein used as conduit?
3	AUTOG_YN	Num	8	B16b. Was alternative autogenous vein used?
4	PROSTH_COND_YN	Num	8	B16c. Was a non-autogenous conduit used?
5	BYPASS_CMPSTVN	Num	8	Bypass using composite vein
6	AKFMRLPPLTL_BYPS	Num	8	Above the Knee Femoropopliteal Bypass
7	BKFMRLPPLTL_BYPS	Num	8	Below the Knee Femoropopliteal Bypass
8	FMRLPPLTL_BYPS	Num	8	Femoropopliteal Bypass
9	FMRLPDLTBL_BYPS	Num	8	Femoral-pedal-tibial Bypass
10	PPLTLPDLTBL_BYPS	Num	8	Popliteal-pedal-Tibial Bypass
11	SFA_ENDO	Num	8	Superficial Femoral Artery (SFA)
12	BTK_ENDO	Num	8	Below the Knee (BTK)
13	POPLTL_ENDO	Num	8	Popliteal
14	TBLSPDLS_ENDO	Num	8	Tibials and pedals
15	ARTHERECTOMY	Num	8	Atherectomy
16	ANGIOPLASTYALONE	Num	8	Angioplasty
17	DRUGCTDBLNANGIOPLASTY	Num	8	Drug-coated balloon angioplasty
18	STENTS	Num	8	Stents
19	DRUGELUTINGSTENTS	Num	8	Drug-eluting stents
20	STENTGRAFTS	Num	8	Stent-grafts
21	SFA_ATH	Num	8	SFA and Atherectomy
22	SFA_PBAA	Num	8	SFA and Angioplasty alone
23	SFA_PBA	Num	8	SFA and Angioplasty
24	SFA_DCB	Num	8	SFA and Drug-coated balloon angioplasty
25	SFA_BMS	Num	8	SFA and Bare metal stents
26	SFA_DES	Num	8	SFA and Drug-eluting stents
27	SFA_SG	Num	8	SFA and Stent-grafts
28	POP_ATH	Num	8	Popliteal and Atherectomy
29	POP_PBAA	Num	8	Popliteal and Angioplasty alone
30	POP_PBA	Num	8	Popliteal and Angioplasty
31	POP_DCB	Num	8	Popliteal and Drug-coated balloon angioplasty
32	POP_BMS	Num	8	Popliteal and Bare metal stents
33	POP_DES	Num	8	Popliteal and Drug-eluting stents
34	POP_SG	Num	8	Popliteal and Stent-grafts
35	TBPD_ATH	Num	8	Tibials/Pedis and Atherectomy
36	TBPD_PBAA	Num	8	Tibials/Pedis andAngioplasty alone

Num	Variable	Type	Len	Label
37	TBPD_PBA	Num	8	Tibials/Pedis andAngioplasty
38	TBPD_DCB	Num	8	Tibials/Pedis and Drug-coated balloon angioplasty
39	TBPD_BMS	Num	8	Tibials/Pedis and Bare metal stents
40	TBPD_DES	Num	8	Tibials/Pedis and Drug-eluting stents
41	TBPD_SG	Num	8	Tibials/Pedis and Stent-grafts
42	ENDO_AORT_THRPY	Num	8	Aortoiliac Endovascular Therapy (Index limb)
43	IPSIL_CDFA_ENDART	Num	8	Common /Deep Femoral Endarderectomy
44	IPSIL_CDFA_ENDO	Num	8	Common /Deep Femoral Endovascular Therapy
45	VASCULAR_SURGEONS	Num	8	Specialty: Vascular Surgeons
46	INTERVENTIONAL_CARDIOLOGISTS	Num	8	Specialty: Interventional Cardiologists
47	INTERVENTIONAL_RADIOLOGISTS	Num	8	Specialty: Interventional Radiologists
48	VASCULAR_MEDICINE	Num	8	Specialty: Vascular Medicine
49	OTHER	Num	8	Specialty: Other

Data Set Name: proc_test.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	ID_PROC_TEST	Num	8	B2. Identify procedure/test:
6	PROC_TEST_DAYSRND	Num	8	Days since randomization - B1. Date of procedure/diagnostic test
7	DIAL_START_DAYSRND	Num	8	Days since randomization - B2a. Start date of dialysis
8	DIAL_STOP_DAYSRND	Num	8	Days since randomization - B2b. Stop date of dialysis

Data Set Name: psmoks.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	CSMOKE	Num	8	B1. Does the subject currently smoke?
6	NPYS	Num	8	B1a. If yes, number of pack-years smoked
7	EVERS	Num	8	B1b. If no, has the subject ever smoked?
8	QUITS	Num	8	B1b1. If yes, how many months ago did the subject quit?
9	QNPYS	Num	8	B1b2. If yes, number of pack years smoked
10	FC_DAYSRND	Num	8	Days since randomization - A2. Date form completed

Data Set Name: rand.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	FACTOR_A	Num	8	B1. Factor A: Clinical Classification
6	FACTOR_B	Num	8	B2. Factor B: Anatomical Classification
7	INDEX_LEG	Num	8	B3. Which leg is the index leg?

Data Set Name: rand_info.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	COHORT	Num	8	Cohort
3	STRATAID	Num	8	Strata Group Id
4	STRATUM	Num	8	Stratum
5	ARM	Num	8	Treatment Group

Data Set Name: rec.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	REC_RECUP	Num	8	A2. Was the subject re-consented under protocol version 5.0?
6	REC_US	Num	8	A2b. Is this a U.S. site?
7	REC_PTINFO	Num	8	A2b1. Did the subject agree to provide Patient Identifiable Information?
8	REC_CON	Num	8	A2b2. Did the subject sign the Anthem consent?
9	REC_DRUP_DAYSRND	Num	8	Days since randomization - A2a. Date of re-consent - under protocol version 5.0

Data Set Name: reco.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	RECO_YN	Num	8	A2. Was the patient re-consented under protocol version 4.1?
6	RECO_DAYSRND	Num	8	Days since randomization - A2a. Date of re-consent

Data Set Name: recontact.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	SUB_RETURN	Num	8	B1. Is the subject actively returning for a study visit?
6	TYPE_DATA	Char	4000	B2. Type of data collection
7	RECONTACT_SC	Num	8	C1. Subject recontact status change
8	RECONTACT_DAYSRND	Num	8	Days since randomization - A1a. Date of Study Recontact form completion
9	RESC_DAYSRND	Num	8	Days since randomization - C2. Date subject study recontact status change

Data Set Name: reint.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	TYPE	Num	8	B1. Type of Intervention or Procedure
6	LEG	Num	8	B3. Which leg?
7	ENDO_LOC	Char	4000	B4a. Location:
8	ENDO_DEVICES	Char	4000	B4b. Devices used:
9	THROMB_SEG	Num	8	B5. What segment underwent surgical thrombectomy?
10	PATCH_ANGIO_LOC	Num	8	B6a. Location:
11	PATCH_TYPE	Num	8	B6b. Type of patch used:
12	ORIGIN	Num	8	B7a. Origin:
13	TARGET	Num	8	B7b. Target:
14	CONDUIT	Num	8	B7c. Conduit type:
15	IMR	Char	1	DCC Only: Check if IMR review required.
16	IMR_OUTCOME	Num	8	C3. Outcome of Review
17	PROC_DAYSRND	Num	8	Days since randomization - B2. Date of Intervention or Procedure
18	IMR_DAYSRND	Num	8	Days since randomization - C1. Date of IMR review

Data Set Name: sf12.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	WHO_COMP	Num	8	A2. Who filled out this quality of life questionnaire?
6	HEALTH	Num	8	B1. In general, would you say your health is:
7	MOD_ACT	Num	8	B2a. Moderate activities such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.
8	STAIRS	Num	8	B2b. Climbing several flights of stairs.
9	ACCOMPLISH	Num	8	B3a. Accomplished less than you would like.
10	ACTIVITIES	Num	8	B3b. Were limited in the kind of work or other activities.
11	ACCOMP_LESS	Num	8	B4a. Accomplished less than you would like.
12	ACTV_LESS	Num	8	B4a. Did work or activities less carefully than usual.
13	NORM_WORK	Num	8	B5. During the <u>past 4 weeks</u>, how much <u>did pain interfere</u> with your normal work (including work outside the home and housework)?
14	CALM	Num	8	B6a. Have you felt calm and peaceful?
15	ENERGY	Num	8	B6b. Did you have a lot of energy?
16	DOWN	Num	8	B6c. Have you felt down-hearted and blue?
17	SOCIAL	Num	8	B7. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting friends, relatives, etc.)?
18	ACCOMPLISH_3	Num	8	B3a. <u>Accomplished less</u> than you would like.
19	ACTIVITIES_3	Num	8	B3b. Were limited in the <u>kind</u> of work or other activities.
20	ACCOMP_LESS_3	Num	8	B4a. <u>Accomplished less</u> than you would like.
21	ACTV_LESS_3	Num	8	B4a. Did work or activities <u>less carefully than usual</u>.
22	MODE_ADMIN	Num	8	A2. Mode of administration:
23	INTERPRET	Num	8	A3. Was an interpreter used?
24	COMP_DAYSRND	Num	8	Days since randomization - A5. Completion Date

Data Set Name: smwt.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	VISIT	Num	8	A2. Visit
6	WALK_TEST_YN	Num	8	B1. Was the six minute walk test performed?
7	REASON_NO_WALK	Num	8	B1a. Reason for NO
8	PRE_HR	Num	8	C1. Sitting Heart Rate (Beats/Min):
9	PRE_SYSTOLIC	Num	8	C2. Sitting Blood Pressure: Systolic (mmHg):
10	PRE_DIASTOLIC	Num	8	C3. Sitting Blood Pressure: Diastolic (mmHg):
11	PRE_O2_SAT	Num	8	C4. Oxygen Saturation (%)
12	BORG_PRIOR	Num	8	C5. Using the BORG scale, how does the subject rate their dyspnea (shortness of breath) before the walk:
13	DISTAN_WALKED	Num	8	D1. Distance Walked
14	WALKED_UN	Num	8	D1a. Unit
15	MINUTE_WALK	Num	8	D2a. Minutes:
16	SECOND_WALK	Num	8	D2b. Seconds:
17	OXYG_USED_YN	Num	8	D3. Was supplemental oxygen used?
18	AID_USED_YN	Num	8	D4. Was a walking aid used?
19	SYMPTOMS_YN	Num	8	D5. Did subject experience any symptoms?
20	AGNINA	Num	8	D5a. Angina
21	LIGHHEADED	Num	8	D5b. Lightheadedness
22	SYNCOPE	Num	8	D5c. Syncope
23	DYSPNEA	Num	8	D5d. Dyspnea
24	FATIGUE	Num	8	D5e. Fatigue
25	JOINT_PAIN	Num	8	D5f. Leg or joint pain
26	INSTABILITY	Num	8	D5g. Instability
27	SYMP_OTH	Num	8	D5h. Other
28	POST_HR	Num	8	E1. Sitting Heart Rate (Beats/Min):
29	POST_SYSTOL	Num	8	E2. Sitting Blood Pressure: Systolic (mmHg):
30	POST_DIAST	Num	8	E3. Sitting Blood Pressure: Diastolic (mmHg):
31	BORG	Num	8	E4. Using the BORG scale, how does the subject rate their dyspnea (shortness of breath) after the walk:
32	POST_O2_SAT	Num	8	E5. Oxygen Saturation (%)
33	ASSES_DAYSRND	Num	8	Days since randomization - B2. Date of assessment

Data Set Name: status_chg.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	REASON	Num	8	B2. Primary reason for status change:
6	DEATH_TIME	Num	8	B2a. Time of Death:
7	WD_DISP	Num	8	B2b. Withdrawal disposition:
8	ANGIO_YN	Num	8	B2a. Was an angiogram performed to determine eligibility?
9	INELIG_YN	Num	8	B2a2. Did the angiogram result indicate ineligibility?
10	WD_AE	Num	8	B2b. Was the patient withdrawn due to an Adverse Event?
11	WD_AE_NO	Num	8	B2b1. If yes, please provide the AE number
12	STATUS_CHG_DAYSRND	Num	8	Days since randomization - B1. Date study status changed or Date of Death
13	ANGIO_DAYSRND	Num	8	Days since randomization - B2a1. Date of Angiogram

Data Set Name: stroke.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	STUDY_DEF	Num	8	B1. Does the event meet the study definition of a stroke?
6	STROKE_CAT	Num	8	B1a. If yes, which category of stroke occurred?

Data Set Name: stroke2.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	STUDY_DEF	Num	8	B1. Does the event meet the study definition of a Stroke?
6	STROKE_CAT	Num	8	B1a. If yes, which category of stroke occurred?

Data Set Name: stroke3.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	STUDY_DEF	Num	8	B1. Does the event meet the study definition of a Stroke?
6	STROKE_CAT	Num	8	B1a. If yes, which category of stroke occurred?

Data Set Name: stroke_o.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	CEC_EVENT	Num	8	A3. Unique Identifier of Event Under Review
6	FULL_COMM	Num	8	A4. Is this a full committee review?
7	STUDY_DEF	Num	8	B1. Does the event meet the study definition of a Stroke?
8	STROKE_CAT	Num	8	B1a. If yes, which category of stroke occurred?
9	EVENT_DAYSRND	Num	8	Days since randomization - A2. Date of Event Under Review

Data Set Name: timetoevent_outcomes.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	TMTO_AAAIOS	Num	8	Time to first above ankle amputation of the index leg while on study (Years)
3	EVNT_AAAIOS	Num	8	Above ankle amputation of the index leg while on study
4	TMTO_AAAITB	Num	8	Time to first above ankle amputation of the index leg while on study, or known to have transtibial amputation by the last day of the trial (Years)
5	EVNT_AAAITB	Num	8	Above ankle amputation of the index leg while on study, or known to have transtibial amputation by the last day of the trial
6	TMTO_AAAISC	Num	8	Time to first above ankle amputation of the index leg while on study, or known to have by the last day of the trial (Years)
7	EVNT_AAAISC	Num	8	Above ankle amputation of the index leg while on study, or known to have by the last day of the trial
8	TMTO_MJREINTIOS	Num	8	Time to first CEC confirmed major intervention of the index leg while on the study (Years)
9	EVNT_MJREINTIOS	Num	8	Major re-intervention of the index leg while on the study
10	TMTO_MNREINTIOS	Num	8	Time to first minor intervention of the index leg while on the study (Years)
11	EVNT_MNREINTIOS	Num	8	Minor re-intervention of the index leg while on the study
12	TMTO_REINTIOS	Num	8	Time to first intervention (both major and minor) of the index leg while on the study (Years)
13	EVNT_REINTIOS	Num	8	Re-intervention (both major and minor) event of the index leg while on the study
14	TMTO_MALEDTH	Num	8	Time to MALE or death event (Years)
15	EVNT_MALEDTH	Num	8	MALE free survivale event
16	TMPRCTO_MALEPOD	Num	8	Time from index procedure to first MALE through EOS, or death event within 30 days of index procedure (Years)
17	EVNTPRC_MALEPOD	Num	8	MALE event between index procedure and EOS, or Death event within 30 days of index procedure
18	TMTO_AFS	Num	8	Time to first above ankle amputation of index limb or death date (Years)
19	EVNT_AFS	Num	8	Above ankle amputation of index limb or death
20	TMTO_RAFS	Num	8	Time to first re-intervention or above ankle amputation of index limb, or death date (Years)
21	EVNT_RAFS	Num	8	Re-intervention or above ankle amputation of index limb or death
22	EVNT_DTH	Num	8	Death Event from randomization through EOS
23	TMTO_DTHYR	Num	8	Time from the date of randomization to death, years
24	EVNTPRC_DTH30DY	Num	8	Death event within 30 days of the index procedure
25	TMPRCTO_DTH30DY	Num	8	Time from the date of index procedure to death, within 30 days of the index procedure.
26	TMTO_MI	Num	8	Time to first MI (Years)
27	EVNT_MI	Num	8	MI Event
28	TMTO_STRK	Num	8	Time to first Stroke (Years)
29	EVNT_STRK	Num	8	Stroke Event
30	TMTO_MACE	Num	8	Time to first MI, Stroke or All cause death (Years)
31	EVNT_MACE	Num	8	MI, Stroke or All cause death event
32	TMTO_MACE30DY	Num	8	Time from randomization to first MI, Stroke or All cause death within 30 days of the index procedure (Days)

Num	Variable	Type	Len	Label
33	EVNT_MACE30DY	Num	8	MI, Stroke or All cause death event within 30 days of the index procedure from the date of randomization
34	LSTVST_DAYSRND	Num	8	Days since randomization

Data Set Name: vasc_exam.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	PAD_YN	Num	8	B1. Is the subject experiencing signs and symptoms of PAD in the index leg currently (baseline or follow-up) or has experienced since the last study visit (follow-up)?
6	CLAUDIC	Num	8	B1a. Ongoing, new or recurrent intermittent claudication
7	REST_PAIN	Num	8	B1b. Ongoing, new or recurrent ischemic rest pain
8	TISS_LOSS	Num	8	B1c. Ongoing, new or recurrent tissue loss
9	DURAT_IND	Num	8	B1d. Duration of signs and symptoms in the index leg
10	IND_HEAL	Num	8	B2. If no signs or symptoms, does the subject have any previously reported wounds that are now healed?
11	FEM_P_IND	Num	8	Index Femoral:
12	FEM_P_NIL	Num	8	Non-Index Femoral:
13	POP_P_IND	Num	8	Index Popliteal:
14	POP_P_NIL	Num	8	Non-index Popliteal:
15	POST_P_IND	Num	8	Index Posterior Tibial:
16	POST_P_NIL	Num	8	Non-index Posterior Tibial:
17	DORS_PED_IND	Num	8	Index Dorsalis Pedis:
18	DORS_PED_NIL	Num	8	Non-index Dorsalis Pedis:
19	GRAFT_IND	Num	8	Index Graft
20	T1_ULCR	Num	8	Toe 1 Ulcers:
21	T1_STATUS	Num	8	Toe 1 Status
22	T1_GANG	Num	8	Toe 1 Gangrene:
23	T2_ULCR	Num	8	Toe 2 Ulcers:
24	T2_STATUS	Num	8	Toe 2 Status
25	T2_GANG	Num	8	Toe 2 Gangrene:
26	T3_ULCR	Num	8	Toe 3 Ulcers:
27	T3_STATUS	Num	8	Toe 3 Status
28	T3_GANG	Num	8	Toe 3 Gangrene:
29	T4_ULCR	Num	8	Toe 4 Ulcers:
30	T4_STATUS	Num	8	Toe 4 Status
31	T4_GANG	Num	8	Toe 4 Gangrene:
32	T5_ULCR	Num	8	Toe 5 Ulcers:
33	T5_STATUS	Num	8	Toe 5 Status
34	T5_GANG	Num	8	Toe 5 Gangrene:
35	FF_ULCR	Num	8	Forefoot Ulcers:

Num	Variable	Type	Len	Label
36	FF_STATUS	Num	8	Forefoot Status
37	FF_GANG	Num	8	Forefoot Gangrene:
38	HF_ULCR	Num	8	Hindfoot Ulcers:
39	HF_STATUS	Num	8	Hindfoot Status
40	HF_GANG	Num	8	Hindfoot Gangrene:
41	AN_ULCR	Num	8	Ankle Ulcers:
42	AN_STATUS	Num	8	Ankle Status
43	AN_GANG	Num	8	Ankle Gangrene:
44	AABK_ULCR	Num	8	Above ankle/below knee Ulcers:
45	AABK_STATUS	Num	8	Above ankle/below knee Status
46	AABK_GANG	Num	8	Above ankle/below knee Gangrene:
47	LESION_LOC	Num	8	D1. Please note the location of the worst lesion.
48	WAGNER	Num	8	D2. Please grade the worst lesion on the index extremity using the Wagner Wound Classification:
49	WIFI	Num	8	D3a. Wound grade:
50	ISCHEMIA	Num	8	D3b. Ischemia grade:
51	INFECTION	Num	8	D3c. Infection grade:
52	CONTRA_LIMB	Num	8	Does patient have Critical Limb Ischemia in the contralateral (non-index) limb?
53	RUTH_4	Num	8	Does patient have ischemic rest pain (Rutherford Class 4)?
54	RUTH_5_6	Num	8	Does patient have tissue loss (Rutherford Class 5 or 6)?
55	ASSESS_DAYSRND	Num	8	Days since randomization - A2. Date of Assessment

Data Set Name: vasc_hx.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	AMP_IND	Num	8	B1. Does the subject have any amputation in the index leg?
6	AMP_LEVEL_IND	Num	8	B1a. If yes, what is the highest level of amputation?
7	AMP_NIL	Num	8	B2. Does the subject have any amputation in the non-index leg?
8	AMP_LEVEL_NIL	Num	8	B2a. If yes, what is the highest level of amputation?
9	PREV_IND	Num	8	C1. Previous vascular intervention to index leg
10	PREV_INF_IND	Num	8	C1a. Previous inflow reconstruction
11	INF_ENDO_IND	Num	8	C1a1. Was the inflow reconstruction endovascular?
12	INF_OPEN_IND	Num	8	C1a2. Was the inflow reconstruction open surgical and >6 months ago?
13	PREV_INFR_IND	Num	8	C1b. Previous infrainguinal reconstruction (>6 months)
14	INFR_ENDO_IND	Num	8	C1b1. Was the infrainguinal reconstruction endovascular?
15	INFR_OPEN_IND	Num	8	C1b2. Was the infrainguinal reconstruction open vascular?
16	EINFL_ANG_IND	Num	8	D1. Angioplasty
17	EINFL_ATH_IND	Num	8	D2. Atherectomy
18	EINFL_STENT_IND	Num	8	D3. Stent
19	EINFL_SG_IND	Num	8	D4. Stent-graft
20	EINFL_OTH_IND	Num	8	D5. Other
21	ABF_IND	Num	8	E1. Aortobifemoral bypass
22	AXBF_IND	Num	8	E2. Axillobifemoral bypass
23	FFB_IND	Num	8	E3. Femoro-Femoral bypass
24	TFB_IND	Num	8	E4. Thoracofemoral bypass
25	FE_IND	Num	8	E5. Femoral endarterectomy
26	OINFL_OTH_IND	Num	8	E6. Other
27	EINFR_ANG_IND	Num	8	F1. Angioplasty
28	EINFR_ATH_IND	Num	8	F2. Atherectomy
29	EINFR_STENT_IND	Num	8	F3. Stent
30	EINFR_SG_IND	Num	8	F4. Stent-graft
31	EINFR_OTH_IND	Num	8	F5. Other
32	FAKPB_IND	Num	8	G1. Femoral to above knee popliteal bypass
33	FAKPBC_IND	Num	8	G1a. Femoral to above knee popliteal bypass conduit
34	ASSESS_DAYSRND	Num	8	Days since randomization - A2. Date of assessment

Data Set Name: vascu_qol.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	WHO_COMP	Num	8	A2. Who filled out this quality of life questionnaire?
6	PAIN	Num	8	B1. In the last two weeks I have had pain in the leg (or foot) when walking ……
7	INJURE	Num	8	B2. In the last two weeks I have been worried that I might injure my leg.....
8	COLD	Num	8	B3. In the last two weeks cold feet have given me …….
9	EXERCISE	Num	8	B4. In the last two weeks, because of the poor circulation to my legs, my ability to take exercise or to play any sports has been …..
10	TIRED_WEAK	Num	8	B5. In the last two weeks my legs have felt tired or weak.....
11	TIME_FRIENDS	Num	8	B6. In the last two weeks, because of the poor circulation to my legs, I have been restricted in spending time with my friends or relatives …..
12	PAIN_NIGHT	Num	8	B7. In the last two weeks I have had pain in the foot (or leg) after going to bed at night …..
13	NUMBNSS	Num	8	B8. In the last two weeks pins and needles or numbness in my leg (or foot) have caused me ….
14	WALK_DIS	Num	8	B9. In the last two weeks the distance I can <u>walk has improved</u> …..
15	WALK_ABIL	Num	8	B10. In the last two weeks, because of the poor circulation to my legs, my ability to walk has been....
16	HOUSEBOUND	Num	8	B11. In the last two weeks being (or becoming) housebound has been a concern of mine …..
17	CIRC_LEGS	Num	8	B12. In the last two weeks I have been concerned about having poor circulation to my legs …..
18	REST_PAIN	Num	8	B13. In the last two weeks I have had pain in the foot (or leg) when I am at rest …..
19	CLIMB_STRS	Num	8	B14. In the last two weeks, because of the poor circulation to my legs, my ability to climb stairs has been …..
20	SOC_ACTVTS	Num	8	B15. In the last two weeks, because of the poor circulation to my legs, my ability to take part in social activities has been …..
21	HOUSE_WRK	Num	8	B16. In the last two weeks, because of the poor circulation to my legs, my ability to perform routine household work has been …..
22	ULCR_PAIN	Num	8	B17. In the last two weeks ulcers in the leg (or foot) have given me pain or distress …..
23	RNG_ACTVTS	Num	8	B18. Because of poor circulation to my legs, the overall range of activities that I would have liked to do in the last two weeks has been …..
24	FRUSTRATED	Num	8	B19. In the last two weeks the poor circulation to the legs have made me feel frustrated …..
25	PAIN_DISCOMFORT	Num	8	B20. In the last two weeks when I do get pain in my leg (or foot) it has given me ….
26	RELY_FRNDS	Num	8	B21. In the last two weeks I have felt guilty about relying on friends or relatives …..
27	SHOPPING	Num	8	B22. In the last two weeks, because of the poor circulation to my legs, my ability to go shopping or carry bags has been …..

Num	Variable	Type	Len	Label
28	WORR_LOS	Num	8	B23. In the last two weeks I have worried I might be in danger of losing a part of my leg or foot
29	DIST_LESS	Num	8	B24. In the last two weeks the distance I can walk <u>has become less</u> …..
30	DEPRESSED	Num	8	B25. In the last two weeks I have been depressed about the poor circulation to my legs …..
31	MODE_ADMIN	Num	8	A2. Mode of administration:
32	INTERPRET	Num	8	A3. Was an interpreter used?
33	COMP_DAYSRND	Num	8	Days since randomization - A5. Form Completion Date

Data Set Name: vein_map.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	SSGSV_YN	Num	8	A3. Is an adequate single segment great saphenous vein available?
6	AUTOGEN_YN	Num	8	A3a. Has an alternative autogenous vein been identified?
7	AUTOG_VEIN	Num	8	A3a1. Which vein?
8	VEIN_SIDE	Num	8	A4. From which side of the body?
9	MAX_DIAM	Num	8	A5. Maximum diameter of the vein (mm):
10	EXAM_DAYSRND	Num	8	Days since randomization - A2. Exam Date

Data Set Name: visit_info.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	VISIT	Num	8	A2. Visit
6	VISIT_STATUS	Num	8	A3. Visit Status
7	REASON	Num	8	A3b. Reason not completed:
8	PHONE_CONTACT	Num	8	A3b2. Number of attempts made to contact subject:
9	VISIT_DAYSRND	Num	8	Days since randomization - A3a. Date of Visit

Data Set Name: visitdc.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	VISC_DAYSRND	Num	8	Days since randomization - A4. Partial Visit Date

Data Set Name: vitals.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	VITALS_YN	Num	8	A2. Were vital signs taken at this visit?
6	HEIGHT	Num	8	B1. Height
7	HEIGHT_UN	Num	8	B1a. Height Units
8	WEIGHT	Num	8	B2. Weight
9	WEIGHT_UN	Num	8	B2a. Weight Units
10	HEART_R8	Num	8	B3. Heart Rate (beats/min.)
11	SBP_R	Num	8	a1. Right Systolic BP
12	DBP_R	Num	8	a2. Right Diastolic BP
13	SBP_L	Num	8	b1. Left Systolic BP
14	DBP_L	Num	8	b2. Left Diastolic BP
15	SYSTOLIC	Num	8	a. Systolic BP:
16	DIASTOLIC	Num	8	b. Diastolic BP:
17	BP_ARM	Num	8	c. Which arm?
18	VITALS_DAYSRND	Num	8	Days since randomization - A3. Date of measurements

Data Set Name: vitalsda.sas7bdat

Num	Variable	Type	Len	Label
1	RANDOM_SUBNUM	Num	8	Deidentified participant ID
2	VISNAME	Char	100	Visit Name
3	PAGENAME	Char	100	Page Name
4	VISITID	Num	8	Visit Id
5	VITAL_ST	Num	8	B1. Is subject known to be deceased?
6	DEATH_DAYSRND	Num	8	Days since randomization - B1a. Date of Death
7	ALIVE_DAYSRND	Num	8	Days since randomization - B3. Date last known alive