

The SAS System

SAS Dataset= AES Dataset Label= Adverse Events

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|-----------------|------|---------|-----------|------------------|
| 1 | SubjID | Subject ID | Num | Z | | |
| | | | | | | |
| 2 | SubjAESeq | Subject AE # | Num | | | |
| | | | | | | |
| 3 | DaysToAE | Days-to-AE | Num | | | |
| | | | | | | |
| 4 | OnsetDt | Onset Date | Num | YYMMDDD | | |
| | | | | | | |
| 5 | Dx | Diagnosis | Char | \$ | | |
| | | | | | | |
| 6 | ShortDx | Short Diagnosis | Char | \$ | | |
| | | | | | | |
| 7 | SeriousInd | Serious | Num | INDVBL | 0 | No |
| | | | | | 1 | Yes |
| | | | | | **OTHER** | |
| | | | | | | |
| 8 | GradeCd | Grade | Num | GRADECD | . | Unknown |
| | | | | | 1 | Mild |
| | | | | | 2 | Moderate |
| | | | | | 3 | Severe |
| | | | | | 4 | Life-Threatening |
| | | | | | 5 | Death |
| | | | | | **OTHER** | Unexpected Value |
| | | | | | | |

The SAS System

SAS Dataset=AES Dataset Label=Adverse Events

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|-----------------|------|-----------|-----------|------------------|
| 9 | OutcomeCd | Outcome | Num | OUTCOMECD | . | Unknown |
| | | | | | 1 | Resolved |
| | | | | | 2 | Ongoing |
| | | | | | 3 | Death |
| | | | | | **OTHER** | Unexpected Value |
| | | | | | | |
| 10 | ResolDt | Resolution Date | Num | YYMMDDD | | |
| | | | | | | |
| 11 | RelatedInd | Related to Tx | Num | INDVBL | 0 | No |
| | | | | | 1 | Yes |
| | | | | | **OTHER** | |
| | | | | | | |
| 12 | SAENotes | SAE Notes | Char | \$ | | |
| | | | | | | |
| 13 | COD | Cause of Death | Char | \$ | | |
| | | | | | | |
| 14 | DeathDt | Death Date | Num | YYMMDDD | | |
| | | | | | | |
| 15 | IRBRepInd | Reported to IRB | Num | INDVBL | 0 | No |
| | | | | | 1 | Yes |
| | | | | | **OTHER** | |
| | | | | | | |
| 16 | IRBRepDt | IRB Report Date | Num | YYMMDDD | | |
| | | | | | | |

The SAS System

SAS Dataset=AKPS Dataset Label=Performance Status

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|----------------|------|--------|-------|--------------|
| 1 | SubjID | Subject ID | Num | Z | | |
| | | | | | | |
| 2 | Wk | Week | Num | | | |
| | | | | | | |
| 3 | AKPS | AKPS | Num | | | |
| | | | | | | |

The SAS System

SAS Dataset=CCI Dataset Label=Charlson Comorbidity Index

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|----------------------------------|------|--------|-------|--------------|
| 1 | SubjID | Subject ID | Num | Z | | |
| | | | | | | |
| 2 | charlson1 | AIDS, Yes=6 | Num | | | |
| | | | | | | |
| 3 | charlson2 | CVD, Yes=1 | Num | | | |
| | | | | | | |
| 4 | charlson3 | COPD, Yes=1 | Num | | | |
| | | | | | | |
| 5 | charlson4 | CHF, Yes=1 | Num | | | |
| | | | | | | |
| 6 | charlson5 | MI, Yes=1 | Num | | | |
| | | | | | | |
| 7 | charlson6 | PVD, Yes=1 | Num | | | |
| | | | | | | |
| 8 | charlson7 | Connective Tissue Disease, Yes=1 | Num | | | |
| | | | | | | |
| 9 | charlson8 | Dementia, Yes=1 | Num | | | |
| | | | | | | |
| 10 | charlson9 | Hemiplegia, Yes=2 | Num | | | |
| | | | | | | |
| 11 | charlson10 | Ulcer, Yes=1 | Num | | | |
| | | | | | | |
| 12 | charlson11 | Diabetes, Yes=1 | Num | | | |
| | | | | | | |

The SAS System

SAS Dataset=CCI Dataset Label=Charlson Comorbidity Index

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|----------------------------------|------|--------|-------|--------------|
| 13 | charlson12 | Diabetes-end organ damage, Yes=2 | Num | | | |
| | | | | | | |
| 14 | charlson13 | Liver Disease-Mild, Yes=1 | Num | | | |
| | | | | | | |
| 15 | charlson14 | Liver Disease-Mod/Severe, Yes=3 | Num | | | |
| | | | | | | |
| 16 | charlson15 | Renal Disease, Yes=2 | Num | | | |
| | | | | | | |
| 17 | charlson16 | Leukemia, Yes=2 | Num | | | |
| | | | | | | |
| 18 | charlson17 | Lymphoma, Yes=2 | Num | | | |
| | | | | | | |
| 19 | charlson18 | Tumor without mets, Yes=2 | Num | | | |
| | | | | | | |
| 20 | charlson19 | Tumor with mets, Yes=6 | Num | | | |
| | | | | | | |
| 21 | charlson20Txt | Other diagnosis | Char | \$ | | |
| | | | | | | |
| 22 | CCI | Charlson Score (0-33) | Num | | | |
| | | | | | | |

The SAS System

SAS Dataset=CVEVENTS Dataset Label=Cardiovascular Events

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|--|------|-----------|-----------|--------------------|
| 1 | SubjID | Subject ID | Num | Z | | |
| | | | | | | |
| 2 | CVEventSeq | Subject CV Event # | Num | | | |
| | | | | | | |
| 3 | EventDt | Event Date | Num | YYMMDDD | | |
| | | | | | | |
| 4 | Wk | Week | Num | | | |
| | | | | | | |
| 5 | CVEventCd | CV Event | Num | CVEVENTCD | . | Unknown |
| | | | | | 1 | CV Hospitalization |
| | | | | | 2 | CV ED Visit |
| | | | | | 3 | CV Procedure |
| | | | | | 4 | New CV Event |
| | | | | | **OTHER** | Unexpected Value |
| | | | | | | |
| 6 | AnyCVEventInd | Any CV Event | Num | INDVBL | 0 | No |
| | | | | | 1 | Yes |
| | | | | | **OTHER** | |
| | | | | | | |
| 7 | DischDt | Discharge Date | Num | YYMMDDD | | |
| | | | | | | |
| 8 | EventDays | Hospitalization/ED Event Duration (days) | Num | | | |
| | | | | | | |

The SAS System

SAS Dataset=DEATHS Dataset Label=Deaths

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|--------------------|------|---------|-----------|--------------|
| 1 | SubjID | Subject ID | Num | Z | | |
| | | | | | | |
| 2 | DeathDt | Death Date | Num | YYMMDDD | | |
| | | | | | | |
| 3 | DaysToDeath | Days to Death | Num | | | |
| | | | | | | |
| 4 | COD | Cause of Death | Char | \$ | | |
| | | | | | | |
| 5 | ShortCOD | Short COD | Char | \$ | | |
| | | | | | | |
| 6 | CVDCODInd | CVD Cause of Death | Num | INDVBL | 0 | No |
| | | | | | 1 | Yes |
| | | | | | **OTHER** | |
| | | | | | | |

The SAS System

SAS Dataset=DT1STCVEVT Dataset Label=Days-to-First CV Event

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|----------------|------|--------------|-----------|----------------------|
| 1 | SubjID | Subject ID | Num | Z | | |
| | | | | | | |
| 2 | SiteID | Site ID | Num | SITEIDABBREV | 1 | ■ |
| | | | | | 2 | ■■ |
| | | | | | 3 | ■■■ |
| | | | | | 4 | ■■■■ |
| | | | | | 5 | ■■■■■ |
| | | | | | 6 | ■■■■■■ |
| | | | | | 7 | ■■■■■■■ |
| | | | | | 8 | ■■■■■■■■ |
| | | | | | 9 | ■■■■■■■■■ |
| | | | | | 10 | ■■■■■■■■■■ |
| | | | | | 11 | ■■■■■■■■■■■ |
| | | | | | 12 | ■■■■■■■■■■■■ |
| | | | | | 13 | ■■■■■■■■■■■■■ |
| | | | | | 14 | ■■■■■■■■■■■■■■ |
| | | | | | 15 | ■■■■■■■■■■■■■■■ |
| | | | | | 99 | TOTAL |
| | | | | | **OTHER** | Unexpected Value |
| | | | | | | |
| 3 | GrpCd | Study Group | Num | GRPCD | . | NA |
| | | | | | 1 | Discontinued Statins |
| | | | | | 2 | Continued Statins |
| | | | | | **OTHER** | Unexpected Value |

The SAS System

SAS Dataset=DT1STCVEVT Dataset Label=Days-to-First CV Event

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|------------------|------------------------|------|-----------|-----------|--------------------|
| | | | | | | |
| 4 | EventDt | Event Date | Num | YYMMDDD | | |
| | | | | | | |
| 5 | CVEvtInd | CV Event | Num | INDVBL | 0 | No |
| | | | | | 1 | Yes |
| | | | | | **OTHER** | |
| | | | | | | |
| 6 | CVEventCd | CV Event | Num | CVEVENTCD | . | Unknown |
| | | | | | 1 | CV Hospitalization |
| | | | | | 2 | CV ED Visit |
| | | | | | 3 | CV Procedure |
| | | | | | 4 | New CV Event |
| | | | | | **OTHER** | Unexpected Value |
| | | | | | | |
| 7 | DTFCVE | Days-to-First CV Event | Num | | | |
| | | | | | | |
| 8 | YesCVDHistoryInd | History of CVD | Num | INDVBL | 0 | No |
| | | | | | 1 | Yes |
| | | | | | **OTHER** | |
| | | | | | | |
| 9 | SexCd | Sex | Num | SEXCD | . | Unknown |
| | | | | | 1 | Male |
| | | | | | 2 | Female |
| | | | | | **OTHER** | Unexpected Value |

The SAS System

SAS Dataset=DT1STCVEVT Dataset Label=Days-to-First CV Event

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|----------------|------|-------------|-----------|---------------------|
| | | | | | | |
| 10 | EthnicityCd | Ethnicity | Num | ETHNICITYCD | . | Unknown |
| | | | | | 1 | Hispanic |
| | | | | | 2 | Not Hispanic |
| | | | | | **OTHER** | Unexpected Value |
| | | | | | | |
| 11 | RaceCd | Race | Num | RACECD | . | Unknown |
| | | | | | 1 | White |
| | | | | | 2 | Black |
| | | | | | 4 | Asian |
| | | | | | 5 | Pacific Islander |
| | | | | | 6 | American Indian |
| | | | | | 7 | Other Race |
| | | | | | 8 | Multiple Races |
| | | | | | **OTHER** | Unexpected Value |
| | | | | | | |
| 12 | EthRaceCd | Ethnicity/Race | Num | ETHRACECD | . | Unknown |
| | | | | | 1 | NH White |
| | | | | | 2 | NH Black |
| | | | | | 3 | Hispanic |
| | | | | | 4 | NH Asian |
| | | | | | 5 | NH Pacific Islander |
| | | | | | 6 | NH American Indian |
| | | | | | 7 | NH Other Race |

The SAS System

SAS Dataset=DT1STCVEVT Dataset Label=Days-to-First CV Event

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|-----------------|------|--------|-----------|-------------------|
| | | | | | 8 | NH Multiple Races |
| | | | | | **OTHER** | Unexpected Value |
| | | | | | | |
| 13 | AgeAtBaseline | Age at Baseline | Num | | | |
| | | | | | | |

The SAS System

SAS Dataset=ENROLLMENT Dataset Label=Enrollment

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|--------------------------|------|---------|-------|--------------|
| 1 | SiteID | Site ID | Num | | | |
| | | | | | | |
| 2 | IRBN | IRB Approved N | Num | COMMA | | |
| | | | | | | |
| 3 | TgtN | Target N (Revised) | Num | | | |
| | | | | | | |
| 4 | MonToStart | Months to Start | Num | | | |
| | | | | | | |
| 5 | SiteStartDt | Site Start Date | Num | YYMMDDD | | |
| | | | | | | |
| 6 | TgtEnrMons | Target Enrollment Months | Num | | | |
| | | | | | | |
| 7 | TgtRate | Target Rate | Num | | | |
| | | | | | | |
| 8 | EnrCnt | Enroll Cnt | Num | COMMA | | |
| | | | | | | |
| 9 | SubjCntDiff | Diff from Target | Num | | | |
| | | | | | | |
| 10 | EnrMons | Months Enroll | Num | | | |
| | | | | | | |
| 11 | EnrRate | Enroll Rate | Num | | | |
| | | | | | | |
| 12 | Subj1Mons | Months to 1st Subject | Num | | | |
| | | | | | | |

The SAS System

SAS Dataset=ENROLLMENT Dataset Label=Enrollment

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|-------------------|---------------------------|------|--------|-------|--------------|
| 13 | Subj1Rate | Rate at 1st Subject | Num | | | |
| | | | | | | |
| 14 | Subj10Mons | Months to 10th Subject | Num | | | |
| | | | | | | |
| 15 | Subj10Rate | Rate at 10th Subject | Num | | | |
| | | | | | | |
| 16 | EnrWI1st3MonCnt | N First 3 Months | Num | | | |
| | | | | | | |
| 17 | EnrWI1st3MonRate | Rate First 3 Months | Num | | | |
| | | | | | | |
| 18 | EnrWILast3MonCnt | N Last 3 Months | Num | | | |
| | | | | | | |
| 19 | EnrWILast3MonRate | Rate Last 3 Months | Num | | | |
| | | | | | | |
| 20 | RateChg | Change in Rate | Num | | | |
| | | | | | | |
| 21 | MonsSinceLastSubj | Months Since Last Subject | Num | | | |
| | | | | | | |

The SAS System

SAS Dataset=ESAS Dataset Label=' '

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|---------------------------|------|--------|-------|--------------|
| 1 | SubjID | Subject ID | Num | Z | | |
| | | | | | | |
| 2 | Wk | Week | Num | | | |
| | | | | | | |
| 3 | ESASrScore | ESASr 9-Item Score (0-90) | Num | | | |
| | | | | | | |
| 4 | ESAS1 | Pain (0-10) | Num | NUM | | |
| | | | | | | |
| 5 | ESAS2 | Fatigue (0-10) | Num | NUM | | |
| | | | | | | |
| 6 | ESAS3 | Nausea (0-10) | Num | NUM | | |
| | | | | | | |
| 7 | ESAS4 | Depression (0-10) | Num | NUM | | |
| | | | | | | |
| 8 | ESAS5 | Anxiousness (0-10) | Num | NUM | | |
| | | | | | | |
| 9 | ESAS6 | Drowsiness (0-10) | Num | NUM | | |
| | | | | | | |
| 10 | ESAS7 | Appetite (0-10) | Num | NUM | | |
| | | | | | | |
| 11 | ESAS8 | Well-Being (0-10) | Num | NUM | | |
| | | | | | | |
| 12 | ESAS9 | Breathing (0-10) | Num | NUM | | |
| | | | | | | |

The SAS System

SAS Dataset=ESAS Dataset Label=' '

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|-----------------|----------------------------------|------|--------|-------|--------------|
| 13 | ESASStatinScore | ESAS Statin 4-Item Score (0-40) | Num | | | |
| | | | | | | |
| 14 | ESAS10 | Muscle Pain (0-10) | Num | NUM | | |
| | | | | | | |
| 15 | ESAS11 | Weakness (0-10) | Num | NUM | | |
| | | | | | | |
| 16 | ESAS12 | Headaches (0-10) | Num | NUM | | |
| | | | | | | |
| 17 | ESAS13 | Fever (0-10) | Num | NUM | | |
| | | | | | | |
| 18 | ESAS13Score | ESAS 13-Item Total Score (0-130) | Num | | | |
| | | | | | | |
| 19 | ESASMiss | # Missing ESAS Items (Of 13) | Num | | | |
| | | | | | | |

The SAS System

SAS Dataset=LONGITENDPTS Dataset Label=Longitudinal Endpoints

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|----------------|------|--------------|-----------|----------------------|
| 1 | SubjID | Subject ID | Num | Z | | |
| | | | | | | |
| 2 | SiteID | Site ID | Num | SITEIDABBREV | 1 | ■ |
| | | | | | 2 | ■■ |
| | | | | | 3 | ■■■ |
| | | | | | 4 | ■■■ |
| | | | | | 5 | ■■■ |
| | | | | | 6 | ■ |
| | | | | | 7 | ■■■ |
| | | | | | 8 | ■■■ |
| | | | | | 9 | ■■■ |
| | | | | | 10 | ■■■■ |
| | | | | | 11 | ■■■ |
| | | | | | 12 | ■■■ |
| | | | | | 13 | ■■■ |
| | | | | | 14 | ■■■ |
| | | | | | 15 | ■ |
| | | | | | 99 | TOTAL |
| | | | | | **OTHER** | Unexpected Value |
| | | | | | | |
| 3 | GrpCd | Study Group | Num | GRPCD | . | NA |
| | | | | | 1 | Discontinued Statins |
| | | | | | 2 | Continued Statins |
| | | | | | **OTHER** | Unexpected Value |

The SAS System

SAS Dataset=LONGITENDPTS Dataset Label=Longitudinal Endpoints

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|-----------------|--------------------------------------|------|--------|-------|--------------|
| | | | | | | |
| 4 | Wk | Week | Num | | | |
| | | | | | | |
| 5 | MQOLOverall | McGill Overall QOL (qst A, 0-10) | Num | | | |
| | | | | | | |
| 6 | MQOLPhys | McGill Physical Symptoms (0-40) | Num | | | |
| | | | | | | |
| 7 | MQOLPsy | McGill Psychological Symptoms (0-40) | Num | | | |
| | | | | | | |
| 8 | MQOLWell | McGill Existential Well-Being (0-60) | Num | | | |
| | | | | | | |
| 9 | MQOLSup | McGill Support (0-20) | Num | | | |
| | | | | | | |
| 10 | MQOLTotal | McGill Total Score (0-160) | Num | | | |
| | | | | | | |
| 11 | ESASrScore | ESASr 9-Item Score (0-90) | Num | | | |
| | | | | | | |
| 12 | ESASStatinScore | ESAS Statin 4-Item Score (0-40) | Num | | | |
| | | | | | | |
| 13 | ESAS13Score | ESAS 13-Item Total Score (0-130) | Num | | | |
| | | | | | | |
| 14 | AKPS | AKPS | Num | | | |
| | | | | | | |
| 15 | MedsTot | Total # of Meds | Num | | | |

The SAS System

SAS Dataset=LONGITENDPTS Dataset Label=Longitudinal Endpoints

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|-------------------|------------------------------------|------|-------------|-----------|-------------------|
| | | | | | | |
| 16 | RegSchedMeds | # of Regularly Scheduled Meds | Num | | | |
| | | | | | | |
| 17 | PRNMedsGTHalfDays | # of PRN meds taken > half of days | Num | | | |
| | | | | | | |
| 18 | PRNMedsLTHalfDays | # of PRN meds taken < half of days | Num | | | |
| | | | | | | |
| 19 | RecHlthCare | Recommend Health Care | Num | RECOMMEND | 1 | Very Unlikely |
| | | | | | 2 | Somewhat Unlikely |
| | | | | | 3 | Unsure |
| | | | | | 4 | Somewhat Likely |
| | | | | | 5 | Very Likely |
| | | | | | **OTHER** | Unexpected Value |
| | | | | | | |
| 20 | YesCVDHistoryInd | History of CVD | Num | INDVBL | 0 | No |
| | | | | | 1 | Yes |
| | | | | | **OTHER** | |
| | | | | | | |
| 21 | SexCd | Sex | Num | SEXCD | . | Unknown |
| | | | | | 1 | Male |
| | | | | | 2 | Female |
| | | | | | **OTHER** | Unexpected Value |
| | | | | | | |
| 22 | EthnicityCd | Ethnicity | Num | ETHNICITYCD | . | Unknown |

The SAS System

SAS Dataset=LONGITENDPTS Dataset Label=Longitudinal Endpoints

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|----------------|------|-----------|-----------|---------------------|
| | | | | | 1 | Hispanic |
| | | | | | 2 | Not Hispanic |
| | | | | | **OTHER** | Unexpected Value |
| | | | | | | |
| 23 | RaceCd | Race | Num | RACECD | . | Unknown |
| | | | | | 1 | White |
| | | | | | 2 | Black |
| | | | | | 4 | Asian |
| | | | | | 5 | Pacific Islander |
| | | | | | 6 | American Indian |
| | | | | | 7 | Other Race |
| | | | | | 8 | Multiple Races |
| | | | | | **OTHER** | Unexpected Value |
| | | | | | | |
| 24 | EthRaceCd | Ethnicity/Race | Num | ETHRACECD | . | Unknown |
| | | | | | 1 | NH White |
| | | | | | 2 | NH Black |
| | | | | | 3 | Hispanic |
| | | | | | 4 | NH Asian |
| | | | | | 5 | NH Pacific Islander |
| | | | | | 6 | NH American Indian |
| | | | | | 7 | NH Other Race |
| | | | | | 8 | NH Multiple Races |
| | | | | | **OTHER** | Unexpected Value |

The SAS System

SAS Dataset=LONGITENDPTS Dataset Label=Longitudinal Endpoints

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|-----------------|------|--------|-------|--------------|
| | | | | | | |
| 25 | AgeAtBaseline | Age at Baseline | Num | | | |
| | | | | | | |

The SAS System

SAS Dataset=MONTHLYENR Dataset Label=Monthly Enrollment

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|--------------|----------------------|--------------------------|-------------|---------------|--------------|---------------------|
| 1 | SiteID | Site ID | Num | | | |
| | | | | | | |
| 2 | EnrYr | Year of Enrollment | Num | | | |
| | | | | | | |
| 3 | EnrMon | Month of Enrollment | Num | | | |
| | | | | | | |
| 4 | YrMon | Year-Month of Enrollment | Num | YYMMD | | |
| | | | | | | |
| 5 | EnrolledCnt | Enrolled | Num | INDVBL | 0 | No |
| | | | | | 1 | Yes |
| | | | | | **OTHER** | |
| | | | | | | |

The SAS System

SAS Dataset=MQOLQ Dataset Label=McGill Quality of Life

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|--------------------------------------|------|--------|-------|--------------|
| 1 | SubjID | Subject ID | Num | Z | | |
| | | | | | | |
| 2 | Wk | Week | Num | | | |
| | | | | | | |
| 3 | MQOLOverall | McGill Overall QOL (qst A, 0-10) | Num | | | |
| | | | | | | |
| 4 | MQOLPhys | McGill Physical Symptoms (0-40) | Num | | | |
| | | | | | | |
| 5 | MQOLQR_B1 | Self-Identified Symptom 1 (0-10) | Num | | | |
| | | | | | | |
| 6 | MQOLQR_B2 | Self-Identified Symptom 2 (0-10) | Num | | | |
| | | | | | | |
| 7 | MQOLQR_B3 | Self-Identified Symptom 3 (0-10) | Num | | | |
| | | | | | | |
| 8 | MQOLQR_B4 | Physical wellbeing (0-10) | Num | | | |
| | | | | | | |
| 9 | MQOLPsy | McGill Psychological Symptoms (0-40) | Num | | | |
| | | | | | | |
| 10 | MQOLQR_C1 | Depressed (0-10) | Num | | | |
| | | | | | | |
| 11 | MQOLQR_C2 | Nervous/Worried (0-10) | Num | | | |
| | | | | | | |
| 12 | MQOLQR_C3 | Sad (0-10) | Num | | | |
| | | | | | | |

The SAS System

SAS Dataset=MQOLQ Dataset Label=McGill Quality of Life

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|--------------------------------------|------|--------|-------|--------------|
| 13 | MQOLQR_C4 | Afraid of future (0-10) | Num | | | |
| | | | | | | |
| 14 | MQOLWell | McGill Existential Well-Being (0-60) | Num | | | |
| | | | | | | |
| 15 | MQOLQC5 | Life-Purpose (0-10) | Num | NUM | | |
| | | | | | | |
| 16 | MQOLQC6 | Life-Achievement (0-10) | Num | NUM | | |
| | | | | | | |
| 17 | MQOLQC7 | Life-Worth (0-10) | Num | NUM | | |
| | | | | | | |
| 18 | MQOLQC8 | Life-Control (0-10) | Num | NUM | | |
| | | | | | | |
| 19 | MQOLQC9 | Self-Worth (0-10) | Num | NUM | | |
| | | | | | | |
| 20 | MQOLQC10 | Time-A Gift (0-10) | Num | NUM | | |
| | | | | | | |
| 21 | MQOLSup | McGill Support (0-20) | Num | | | |
| | | | | | | |
| 22 | MQOLQC11 | World is Caring (0-10) | Num | NUM | | |
| | | | | | | |
| 23 | MQOLQC12 | Supported (0-10) | Num | NUM | | |
| | | | | | | |
| 24 | MQOLTotal | McGill Total Score (0-160) | Num | | | |
| | | | | | | |

The SAS System

SAS Dataset=POLYPHARMACY Dataset Label=' '

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|-------------------|------------------------------------|------|--------|-------|--------------|
| 1 | SubjID | Subject ID | Num | Z | | |
| | | | | | | |
| 2 | Wk | Week | Num | | | |
| | | | | | | |
| 3 | MedsTot | Total # of Meds | Num | | | |
| | | | | | | |
| 4 | RegSchedMeds | # of Regularly Scheduled Meds | Num | | | |
| | | | | | | |
| 5 | PRNMedsGTHalfDays | # of PRN meds taken > half of days | Num | | | |
| | | | | | | |
| 6 | PRNMedsLTHalfDays | # of PRN meds taken < half of days | Num | | | |
| | | | | | | |

The SAS System

SAS Dataset=PRIMENDPT Dataset Label=Primary Endpoint

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|------------------|----------------------|------|--------|-----------|--------------|
| 1 | SubjID | Subject ID | Num | Z | | |
| | | | | | | |
| 2 | DiedIfEnrInd | Died | Num | INDVBL | 0 | No |
| | | | | | 1 | Yes |
| | | | | | **OTHER** | |
| | | | | | | |
| 3 | DeathWI60DaysInd | Death Within 60 Days | Num | INDVBL | 0 | No |
| | | | | | 1 | Yes |
| | | | | | **OTHER** | |
| | | | | | | |
| 4 | DaysOnStudy | Days On Study | Num | | | |
| | | | | | | |

The SAS System

SAS Dataset=RECOMMEND Dataset Label=Recommend Health Care

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|-----------------------|------|-----------|-----------|-------------------|
| 1 | SubjID | Subject ID | Num | Z | | |
| | | | | | | |
| 2 | Wk | Week | Num | | | |
| | | | | | | |
| 3 | RecHlthCare | Recommend Health Care | Num | RECOMMEND | 1 | Very Unlikely |
| | | | | | 2 | Somewhat Unlikely |
| | | | | | 3 | Unsure |
| | | | | | 4 | Somewhat Likely |
| | | | | | 5 | Very Likely |
| | | | | | **OTHER** | Unexpected Value |
| | | | | | | |

The SAS System

SAS Dataset=SUBJFLOW Dataset Label=Subject Flow

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|----------------|------|--------------|-----------|------------------|
| 1 | SubjID | Subject ID | Num | Z | | |
| | | | | | | |
| 2 | SiteID | Site ID | Num | SITEIDABBREV | 1 | ■ |
| | | | | | 2 | ■■ |
| | | | | | 3 | ■■■ |
| | | | | | 4 | ■■■■ |
| | | | | | 5 | ■■■■■ |
| | | | | | 6 | ■■■■■■ |
| | | | | | 7 | ■■■■■■■ |
| | | | | | 8 | ■■■■■■■■ |
| | | | | | 9 | ■■■■■■■■■ |
| | | | | | 10 | ■■■■■■■■■■ |
| | | | | | 11 | ■■■■■■■■■■■ |
| | | | | | 12 | ■■■■■■■■■■■■ |
| | | | | | 13 | ■■■■■■■■■■■■■ |
| | | | | | 14 | ■■■■■■■■■■■■■■ |
| | | | | | 15 | ■■■■■■■■■■■■■■■ |
| | | | | | 99 | TOTAL |
| | | | | | **OTHER** | Unexpected Value |
| | | | | | | |
| 3 | ScreenedInd | Screened | Num | INDVBL | 0 | No |
| | | | | | 1 | Yes |
| | | | | | **OTHER** | |
| | | | | | | |

The SAS System

SAS Dataset=SUBJFLOW Dataset Label=Subject Flow

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|--------------------|----------------------|------|---------------|-------|--|
| 4 | FailScreenReasonCd | Reason Failed Screen | Num | SUBJENDSTEPCD | . | NA |
| | | | | | 0.1 | Step 0 - Failed Screen - Form A, Part A, Q 1 - Age < 18 years |
| | | | | | 0.2 | Step 0 - Failed Screen - Form A, Part A, Q 2 - No progressive life-limiting illness |
| | | | | | 0.3 | Step 0 - Failed Screen - Form A, Part A, Q 3 - Not on a statin for at least 3 months |
| | | | | | 0.4 | Step 0 - Failed Screen - Form A, Part A, Q 4 - Life expectancy less than 1 month |
| | | | | | 0.5 | Step 0 - Failed Screen - Form A, Part A, Q 5 - Not English proficient |
| | | | | | 0.6 | Step 0 - Failed Screen - Form A, Part A, Q 7 - Barrier to approaching patient |
| | | | | | 1.1 | Step 1 - Ineligible - Form A, Part B, Q 2 - No declining function or AKPS at 80+ |
| | | | | | 1.2 | Step 1 - Ineligible - Form A, Part B, Q 3 - Requires statin drugs |
| | | | | | 1.3 | Step 1 - Ineligible - Form A, Part B, Q 4 - Contraindications |
| | | | | | 2.1 | Step 2.1 - Not Enrolled - Form A, Part B, Q 1 - Physician unwilling |
| | | | | | 2.2 | Step 2.1 - Not Enrolled - Form A, Part B, Q 7 - Subject unwilling |
| | | | | | 2.3 | Step 2.1 - Not Enrolled - Form A, Part B, Q 8 - Other barrier |
| | | | | | 2.4 | Step 2.2 - Not Enrolled - Not consented |
| | | | | | 2.5 | Step 2.2 - Not Enrolled - No valid signature |
| | | | | | 2.6 | Step 2.2 - Not Enrolled - Missing consent date |
| | | | | | 2.7 | Step 2.3 - Not Enrolled - Not randomized |
| | | | | | 3.1 | Step 3 - Withdrawal - Reason unknown |

The SAS System

SAS Dataset=SUBJFLOW Dataset Label=Subject Flow

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|-----------------|-------------------------------------|------|--------|-----------|---|
| | | | | | 3.2 | Step 3 - Withdrawal - Subject refusal to continue |
| | | | | | 3.3 | Step 3 - Withdrawal - Family requested discontinuation |
| | | | | | 3.4 | Step 3 - Withdrawal - Physician requested discontinuation |
| | | | | | 3.5 | Step 3 - Withdrawal - Subject unable to continue |
| | | | | | 3.6 | Step 3 - Withdrawal - AE requires discontinuation |
| | | | | | 3.7 | Step 3 - Withdrawal - Initial eligibility incorrect |
| | | | | | 4.1 | Step 4 - Completer - Died during study |
| | | | | | 4.2 | Step 4 - Completer - 1 year on study |
| | | | | | 4.3 | Step 4 - Completer - < 1 year on study |
| | | | | | **OTHER** | Unexpected Value |
| | | | | | | |
| 5 | PassScreenInd | Passed Screen | Num | INDVBL | 0 | No |
| | | | | | 1 | Yes |
| | | | | | **OTHER** | |
| | | | | | | |
| 6 | MetEligCrit1Ind | Met Elig Crit 1: Has Declining Fcn | Num | INDVBL | 0 | No |
| | | | | | 1 | Yes |
| | | | | | **OTHER** | |
| | | | | | | |
| 7 | MetEligCrit2Ind | Met Elig Crit 2: Statins Not Needed | Num | INDVBL | 0 | No |
| | | | | | 1 | Yes |
| | | | | | **OTHER** | |

The SAS System

SAS Dataset=SUBJFLOW Dataset Label=Subject Flow

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|-----------------|---------------------------------------|------|---------------|-----------|--|
| 8 | MetEligCrit3Ind | Met Elig Crit 3: No Contraindications | Num | INDVBL | 0 | No |
| | | | | | 1 | Yes |
| | | | | | **OTHER** | |
| 9 | IneligReasonCd | Reason Ineligible | Num | SUBJENDSTEPCD | . | NA |
| | | | | | 0.1 | Step 0 - Failed Screen - Form A, Part A, Q 1 - Age < 18 years |
| | | | | | 0.2 | Step 0 - Failed Screen - Form A, Part A, Q 2 - No progressive life-limiting illness |
| | | | | | 0.3 | Step 0 - Failed Screen - Form A, Part A, Q 3 - Not on a statin for at least 3 months |
| | | | | | 0.4 | Step 0 - Failed Screen - Form A, Part A, Q 4 - Life expectancy less than 1 month |
| | | | | | 0.5 | Step 0 - Failed Screen - Form A, Part A, Q 5 - Not English proficient |
| | | | | | 0.6 | Step 0 - Failed Screen - Form A, Part A, Q 7 - Barrier to approaching patient |
| | | | | | 1.1 | Step 1 - Ineligible - Form A, Part B, Q 2 - No declining function or AKPS at 80+ |
| | | | | | 1.2 | Step 1 - Ineligible - Form A, Part B, Q 3 - Requires statin drugs |
| | | | | | 1.3 | Step 1 - Ineligible - Form A, Part B, Q 4 - Contraindications |
| | | | | | 2.1 | Step 2.1 - Not Enrolled - Form A, Part B, Q 1 - Physician unwilling |
| | | | | | 2.2 | Step 2.1 - Not Enrolled - Form A, Part B, Q 7 - Subject unwilling |

The SAS System

SAS Dataset=SUBJFLOW Dataset Label=Subject Flow

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------------|---------------------------------------|------|--------|-----------|---|
| | | | | | 2.3 | Step 2.1 - Not Enrolled - Form A, Part B, Q 8 - Other barrier |
| | | | | | 2.4 | Step 2.2 - Not Enrolled - Not consented |
| | | | | | 2.5 | Step 2.2 - Not Enrolled - No valid signature |
| | | | | | 2.6 | Step 2.2 - Not Enrolled - Missing consent date |
| | | | | | 2.7 | Step 2.3 - Not Enrolled - Not randomized |
| | | | | | 3.1 | Step 3 - Withdrawal - Reason unknown |
| | | | | | 3.2 | Step 3 - Withdrawal - Subject refusal to continue |
| | | | | | 3.3 | Step 3 - Withdrawal - Family requested discontinuation |
| | | | | | 3.4 | Step 3 - Withdrawal - Physician requested discontinuation |
| | | | | | 3.5 | Step 3 - Withdrawal - Subject unable to continue |
| | | | | | 3.6 | Step 3 - Withdrawal - AE requires discontinuation |
| | | | | | 3.7 | Step 3 - Withdrawal - Initial eligibility incorrect |
| | | | | | 4.1 | Step 4 - Completer - Died during study |
| | | | | | 4.2 | Step 4 - Completer - 1 year on study |
| | | | | | 4.3 | Step 4 - Completer - < 1 year on study |
| | | | | | **OTHER** | Unexpected Value |
| | | | | | | |
| 10 | EligIfPassScreenInd | Eligible | Num | INDVBL | 0 | No |
| | | | | | 1 | Yes |
| | | | | | **OTHER** | |
| | | | | | | |
| 11 | PassEnrBarr1Ind | Pass Enr Barr 1: Physician Willing | Num | INDVBL | 0 | No |

The SAS System

SAS Dataset=SUBJFLOW Dataset Label=Subject Flow

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------------|--------------------------------------|------|----------------|-----------|------------------|
| | | | | | 1 | Yes |
| | | | | | **OTHER** | |
| | | | | | | |
| 12 | PassEnrBarr2Ind | Pass Enr Barr 2: Subject Willing | Num | INDVBL | 0 | No |
| | | | | | 1 | Yes |
| | | | | | **OTHER** | |
| | | | | | | |
| 13 | PassEnrBarr3Ind | Pass Enr Barr 3: No Other Barrier | Num | INDVBL | 0 | No |
| | | | | | 1 | Yes |
| | | | | | **OTHER** | |
| | | | | | | |
| 14 | WillingIfEligInd | Willing | Num | INDVBLMISSISNA | . | NA |
| | | | | | 0 | No |
| | | | | | 1 | Yes |
| | | | | | **OTHER** | Unexpected Value |
| | | | | | | |
| 15 | ConsentIfWillingInd | Consented | Num | INDVBLMISSISNA | . | NA |
| | | | | | 0 | No |
| | | | | | 1 | Yes |
| | | | | | **OTHER** | Unexpected Value |
| | | | | | | |
| 16 | ConsentDt | Consent Date | Num | YYMMDDD | | |
| | | | | | | |

The SAS System

SAS Dataset=SUBJFLOW Dataset Label=Subject Flow

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------------|---------------------|------|---------------|-------|--|
| 17 | NotEnrolledReasonCd | Reason Not Enrolled | Num | SUBJENDSTEPCD | . | NA |
| | | | | | 0.1 | Step 0 - Failed Screen - Form A, Part A, Q 1 - Age < 18 years |
| | | | | | 0.2 | Step 0 - Failed Screen - Form A, Part A, Q 2 - No progressive life-limiting illness |
| | | | | | 0.3 | Step 0 - Failed Screen - Form A, Part A, Q 3 - Not on a statin for at least 3 months |
| | | | | | 0.4 | Step 0 - Failed Screen - Form A, Part A, Q 4 - Life expectancy less than 1 month |
| | | | | | 0.5 | Step 0 - Failed Screen - Form A, Part A, Q 5 - Not English proficient |
| | | | | | 0.6 | Step 0 - Failed Screen - Form A, Part A, Q 7 - Barrier to approaching patient |
| | | | | | 1.1 | Step 1 - Ineligible - Form A, Part B, Q 2 - No declining function or AKPS at 80+ |
| | | | | | 1.2 | Step 1 - Ineligible - Form A, Part B, Q 3 - Requires statin drugs |
| | | | | | 1.3 | Step 1 - Ineligible - Form A, Part B, Q 4 - Contraindications |
| | | | | | 2.1 | Step 2.1 - Not Enrolled - Form A, Part B, Q 1 - Physician unwilling |
| | | | | | 2.2 | Step 2.1 - Not Enrolled - Form A, Part B, Q 7 - Subject unwilling |
| | | | | | 2.3 | Step 2.1 - Not Enrolled - Form A, Part B, Q 8 - Other barrier |
| | | | | | 2.4 | Step 2.2 - Not Enrolled - Not consented |
| | | | | | 2.5 | Step 2.2 - Not Enrolled - No valid signature |
| | | | | | 2.6 | Step 2.2 - Not Enrolled - Missing consent date |
| | | | | | 2.7 | Step 2.3 - Not Enrolled - Not randomized |

The SAS System

SAS Dataset=SUBJFLOW Dataset Label=Subject Flow

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|--------------------|------|---------|-----------|---|
| | | | | | 3.1 | Step 3 - Withdrawal - Reason unknown |
| | | | | | 3.2 | Step 3 - Withdrawal - Subject refusal to continue |
| | | | | | 3.3 | Step 3 - Withdrawal - Family requested discontinuation |
| | | | | | 3.4 | Step 3 - Withdrawal - Physician requested discontinuation |
| | | | | | 3.5 | Step 3 - Withdrawal - Subject unable to continue |
| | | | | | 3.6 | Step 3 - Withdrawal - AE requires discontinuation |
| | | | | | 3.7 | Step 3 - Withdrawal - Initial eligibility incorrect |
| | | | | | 4.1 | Step 4 - Completer - Died during study |
| | | | | | 4.2 | Step 4 - Completer - 1 year on study |
| | | | | | 4.3 | Step 4 - Completer - < 1 year on study |
| | | | | | **OTHER** | Unexpected Value |
| | | | | | | |
| 18 | EnrolledInd | Enrolled | Num | INDVBL | 0 | No |
| | | | | | 1 | Yes |
| | | | | | **OTHER** | |
| | | | | | | |
| 19 | EnrollDt | Enrollment Date | Num | YYMMDDD | | |
| | | | | | | |
| 20 | GrpCd | Study Group | Num | GRPCD | . | NA |
| | | | | | 1 | Discontinued Statins |
| | | | | | 2 | Continued Statins |
| | | | | | **OTHER** | Unexpected Value |
| | | | | | | |
| 21 | RandDt | Randomization Date | Num | YYMMDDD | | |

The SAS System

SAS Dataset=SUBJFLOW Dataset Label=Subject Flow

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|--------------------|-----------------------|------|----------------|-----------|--|
| | | | | | | |
| 22 | YesCVDHistoryInd | History of CVD | Num | INDVBL | 0 | No |
| | | | | | 1 | Yes |
| | | | | | **OTHER** | |
| | | | | | | |
| 23 | WithdrawnIfEnrInd | Withdrawn | Num | INDVBLMISSISNA | . | NA |
| | | | | | 0 | No |
| | | | | | 1 | Yes |
| | | | | | **OTHER** | Unexpected Value |
| | | | | | | |
| 24 | WithdrawDt | Withdraw Date | Num | YYMMDDD | | |
| | | | | | | |
| 25 | DaysToWithdraw | Days to Withdraw | Num | | | |
| | | | | | | |
| 26 | WithdrawalReasonCd | Reason for Withdrawal | Num | SUBJENDSTEPCD | . | NA |
| | | | | | 0.1 | Step 0 - Failed Screen - Form A, Part A, Q 1 - Age < 18 years |
| | | | | | 0.2 | Step 0 - Failed Screen - Form A, Part A, Q 2 - No progressive life-limiting illness |
| | | | | | 0.3 | Step 0 - Failed Screen - Form A, Part A, Q 3 - Not on a statin for at least 3 months |
| | | | | | 0.4 | Step 0 - Failed Screen - Form A, Part A, Q 4 - Life expectancy less than 1 month |
| | | | | | 0.5 | Step 0 - Failed Screen - Form A, Part A, Q 5 - Not English proficient |
| | | | | | 0.6 | Step 0 - Failed Screen - Form A, Part A, Q 7 - Barrier to approaching patient |

The SAS System

SAS Dataset=SUBJFLOW Dataset Label=Subject Flow

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|----------------|------|--------|-----------|--|
| | | | | | 1.1 | Step 1 - Ineligible - Form A, Part B, Q 2 - No declining function or AKPS at 80+ |
| | | | | | 1.2 | Step 1 - Ineligible - Form A, Part B, Q 3 - Requires statin drugs |
| | | | | | 1.3 | Step 1 - Ineligible - Form A, Part B, Q 4 - Contraindications |
| | | | | | 2.1 | Step 2.1 - Not Enrolled - Form A, Part B, Q 1 - Physician unwilling |
| | | | | | 2.2 | Step 2.1 - Not Enrolled - Form A, Part B, Q 7 - Subject unwilling |
| | | | | | 2.3 | Step 2.1 - Not Enrolled - Form A, Part B, Q 8 - Other barrier |
| | | | | | 2.4 | Step 2.2 - Not Enrolled - Not consented |
| | | | | | 2.5 | Step 2.2 - Not Enrolled - No valid signature |
| | | | | | 2.6 | Step 2.2 - Not Enrolled - Missing consent date |
| | | | | | 2.7 | Step 2.3 - Not Enrolled - Not randomized |
| | | | | | 3.1 | Step 3 - Withdrawal - Reason unknown |
| | | | | | 3.2 | Step 3 - Withdrawal - Subject refusal to continue |
| | | | | | 3.3 | Step 3 - Withdrawal - Family requested discontinuation |
| | | | | | 3.4 | Step 3 - Withdrawal - Physician requested discontinuation |
| | | | | | 3.5 | Step 3 - Withdrawal - Subject unable to continue |
| | | | | | 3.6 | Step 3 - Withdrawal - AE requires discontinuation |
| | | | | | 3.7 | Step 3 - Withdrawal - Initial eligibility incorrect |
| | | | | | 4.1 | Step 4 - Completer - Died during study |
| | | | | | 4.2 | Step 4 - Completer - 1 year on study |
| | | | | | 4.3 | Step 4 - Completer - < 1 year on study |
| | | | | | **OTHER** | Unexpected Value |
| | | | | | | |
| 27 | DiedIfEnrInd | Died | Num | INDVBL | 0 | No |

The SAS System

SAS Dataset=SUBJFLOW Dataset Label=Subject Flow

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|-------------------|------------------|------|---------------|-----------|--|
| | | | | | 1 | Yes |
| | | | | | **OTHER** | |
| | | | | | | |
| 28 | DeathDt | Death Date | Num | YYMMDDD | | |
| | | | | | | |
| 29 | DaysToDeath | Days to Death | Num | | | |
| | | | | | | |
| 30 | CompleterIfEnrInd | Completer | Num | INDVBL | 0 | No |
| | | | | | 1 | Yes |
| | | | | | **OTHER** | |
| | | | | | | |
| 31 | ActiveIfEnrInd | Active On Study | Num | INDVBL | 0 | No |
| | | | | | 1 | Yes |
| | | | | | **OTHER** | |
| | | | | | | |
| 32 | SubjEndStepCd | Subject End Step | Num | SUBJENDSTEPCD | . | NA |
| | | | | | 0.1 | Step 0 - Failed Screen - Form A, Part A, Q 1 - Age < 18 years |
| | | | | | 0.2 | Step 0 - Failed Screen - Form A, Part A, Q 2 - No progressive life-limiting illness |
| | | | | | 0.3 | Step 0 - Failed Screen - Form A, Part A, Q 3 - Not on a statin for at least 3 months |
| | | | | | 0.4 | Step 0 - Failed Screen - Form A, Part A, Q 4 - Life expectancy less than 1 month |
| | | | | | 0.5 | Step 0 - Failed Screen - Form A, Part A, Q 5 - Not English proficient |

The SAS System

SAS Dataset=SUBJFLOW Dataset Label=Subject Flow

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|----------------|------|--------|-----------|--|
| | | | | | 0.6 | Step 0 - Failed Screen - Form A, Part A, Q 7 - Barrier to approaching patient |
| | | | | | 1.1 | Step 1 - Ineligible - Form A, Part B, Q 2 - No declining function or AKPS at 80+ |
| | | | | | 1.2 | Step 1 - Ineligible - Form A, Part B, Q 3 - Requires statin drugs |
| | | | | | 1.3 | Step 1 - Ineligible - Form A, Part B, Q 4 - Contraindications |
| | | | | | 2.1 | Step 2.1 - Not Enrolled - Form A, Part B, Q 1 - Physician unwilling |
| | | | | | 2.2 | Step 2.1 - Not Enrolled - Form A, Part B, Q 7 - Subject unwilling |
| | | | | | 2.3 | Step 2.1 - Not Enrolled - Form A, Part B, Q 8 - Other barrier |
| | | | | | 2.4 | Step 2.2 - Not Enrolled - Not consented |
| | | | | | 2.5 | Step 2.2 - Not Enrolled - No valid signature |
| | | | | | 2.6 | Step 2.2 - Not Enrolled - Missing consent date |
| | | | | | 2.7 | Step 2.3 - Not Enrolled - Not randomized |
| | | | | | 3.1 | Step 3 - Withdrawal - Reason unknown |
| | | | | | 3.2 | Step 3 - Withdrawal - Subject refusal to continue |
| | | | | | 3.3 | Step 3 - Withdrawal - Family requested discontinuation |
| | | | | | 3.4 | Step 3 - Withdrawal - Physician requested discontinuation |
| | | | | | 3.5 | Step 3 - Withdrawal - Subject unable to continue |
| | | | | | 3.6 | Step 3 - Withdrawal - AE requires discontinuation |
| | | | | | 3.7 | Step 3 - Withdrawal - Initial eligibility incorrect |
| | | | | | 4.1 | Step 4 - Completer - Died during study |
| | | | | | 4.2 | Step 4 - Completer - 1 year on study |
| | | | | | 4.3 | Step 4 - Completer - < 1 year on study |
| | | | | | **OTHER** | Unexpected Value |

The SAS System

SAS Dataset=SUBJFLOW Dataset Label=Subject Flow

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|----------------------|-----------------------------|------|-----------|-------|----------------|
| | | | | | | |
| 33 | LastConfirmedAliveDt | Latest Date Confirmed Alive | Num | YYMMDDD | | |
| | | | | | | |
| 34 | LastWk | Last Week of Follow-Up | Num | | | |
| | | | | | | |
| 35 | StudyEndDt | Study End Date | Num | YYMMDDD | | |
| | | | | | | |
| 36 | DaysOnStudy | Days On Study | Num | | | |
| | | | | | | |
| 37 | DaysSinceEnrollment | Days Since Enrollment | Num | | | |
| | | | | | | |
| 38 | eligA1 | Patient-Age >= 18 | Num | LOGICALNA | 0 | No |
| | | | | | 1 | Yes |
| | | | | | 9 | Not Applicable |
| | | | | | .A | Not Applicable |
| | | | | | .D | Not Done |
| | | | | | .K | Unknown |
| | | | | | -97 | Not Done |
| | | | | | -98 | Unknown |
| | | | | | -99 | Not Applicable |
| | | | | | | |
| 39 | eligA2 | Life Limiting- Illness | Num | LOGICALNA | 0 | No |
| | | | | | 1 | Yes |
| | | | | | 9 | Not Applicable |

The SAS System

SAS Dataset=SUBJFLOW Dataset Label=Subject Flow

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|---------------------------|------|-----------|-------|----------------|
| | | | | | .A | Not Applicable |
| | | | | | .D | Not Done |
| | | | | | .K | Unknown |
| | | | | | -97 | Not Done |
| | | | | | -98 | Unknown |
| | | | | | -99 | Not Applicable |
| | | | | | | |
| 40 | eligA3 | On Statin->= 3 months | Num | LOGICALNA | 0 | No |
| | | | | | 1 | Yes |
| | | | | | 9 | Not Applicable |
| | | | | | .A | Not Applicable |
| | | | | | .D | Not Done |
| | | | | | .K | Unknown |
| | | | | | -97 | Not Done |
| | | | | | -98 | Unknown |
| | | | | | -99 | Not Applicable |
| | | | | | | |
| 41 | eligA4 | Life expectancy-> 1 month | Num | LOGICALNA | 0 | No |
| | | | | | 1 | Yes |
| | | | | | 9 | Not Applicable |
| | | | | | .A | Not Applicable |
| | | | | | .D | Not Done |
| | | | | | .K | Unknown |
| | | | | | -97 | Not Done |

The SAS System

SAS Dataset=SUBJFLOW Dataset Label=Subject Flow

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|-----------------------------|------|----------------|-------|----------------|
| | | | | | -98 | Unknown |
| | | | | | -99 | Not Applicable |
| | | | | | | |
| 42 | eligA5 | Patient-Speak/Read English | Num | LOGICALNA | 0 | No |
| | | | | | 1 | Yes |
| | | | | | 9 | Not Applicable |
| | | | | | .A | Not Applicable |
| | | | | | .D | Not Done |
| | | | | | .K | Unknown |
| | | | | | -97 | Not Done |
| | | | | | -98 | Unknown |
| | | | | | -99 | Not Applicable |
| | | | | | | |
| 43 | eligA7 | Barrier to-Approach Patient | Num | LOGICALNA | 0 | No |
| | | | | | 1 | Yes |
| | | | | | 9 | Not Applicable |
| | | | | | .A | Not Applicable |
| | | | | | .D | Not Done |
| | | | | | .K | Unknown |
| | | | | | -97 | Not Done |
| | | | | | -98 | Unknown |
| | | | | | -99 | Not Applicable |
| | | | | | | |
| 44 | eligB1 | Physician-Willing to enroll | Num | LOGICALUNKNOWN | 0 | No |

The SAS System

SAS Dataset=SUBJFLOW Dataset Label=Subject Flow

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|---------------------------------------|------|----------------|-------|----------------|
| | | | | | 1 | Yes |
| | | | | | 9 | Unknown |
| | | | | | .A | Not Applicable |
| | | | | | .D | Not Done |
| | | | | | .K | Unknown |
| | | | | | -97 | Not Done |
| | | | | | -98 | Unknown |
| | | | | | -99 | Not Applicable |
| | | | | | | |
| 45 | eligB2 | Declining function status-and AKPS<80 | Num | LOGICALUNKNOWN | 0 | No |
| | | | | | 1 | Yes |
| | | | | | 9 | Unknown |
| | | | | | .A | Not Applicable |
| | | | | | .D | Not Done |
| | | | | | .K | Unknown |
| | | | | | -97 | Not Done |
| | | | | | -98 | Unknown |
| | | | | | -99 | Not Applicable |
| | | | | | | |
| 46 | eligB3 | Requires ongoing- statin therapy | Num | LOGICALUNKNOWN | 0 | No |
| | | | | | 1 | Yes |
| | | | | | 9 | Unknown |
| | | | | | .A | Not Applicable |
| | | | | | .D | Not Done |

The SAS System

SAS Dataset=SUBJFLOW Dataset Label=Subject Flow

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|----------------------------------|------|----------------|-------|----------------|
| | | | | | .K | Unknown |
| | | | | | -97 | Not Done |
| | | | | | -98 | Unknown |
| | | | | | -99 | Not Applicable |
| | | | | | | |
| 47 | eligB4 | Contraindications-Statin Therapy | Num | LOGICALUNKNOWN | 0 | No |
| | | | | | 1 | Yes |
| | | | | | 9 | Unknown |
| | | | | | .A | Not Applicable |
| | | | | | .D | Not Done |
| | | | | | .K | Unknown |
| | | | | | -97 | Not Done |
| | | | | | -98 | Unknown |
| | | | | | -99 | Not Applicable |
| | | | | | | |
| 48 | eligB7 | Participation-willing to discuss | Num | LOGICALUNKNOWN | 0 | No |
| | | | | | 1 | Yes |
| | | | | | 9 | Unknown |
| | | | | | .A | Not Applicable |
| | | | | | .D | Not Done |
| | | | | | .K | Unknown |
| | | | | | -97 | Not Done |
| | | | | | -98 | Unknown |
| | | | | | -99 | Not Applicable |

The SAS System

SAS Dataset=SUBJFLOW Dataset Label=Subject Flow

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|---------------------------|------|----------------|-------|----------------|
| | | | | | | |
| 49 | eligB8 | Barrier to- Participation | Num | LOGICALUNKNOWN | 0 | No |
| | | | | | 1 | Yes |
| | | | | | 9 | Unknown |
| | | | | | .A | Not Applicable |
| | | | | | .D | Not Done |
| | | | | | .K | Unknown |
| | | | | | -97 | Not Done |
| | | | | | -98 | Unknown |
| | | | | | -99 | Not Applicable |
| | | | | | | |
| 50 | eligC1 | Informed consent-Provided | Num | LOGICALNA | 0 | No |
| | | | | | 1 | Yes |
| | | | | | 9 | Not Applicable |
| | | | | | .A | Not Applicable |
| | | | | | .D | Not Done |
| | | | | | .K | Unknown |
| | | | | | -97 | Not Done |
| | | | | | -98 | Unknown |
| | | | | | -99 | Not Applicable |
| | | | | | | |
| 51 | eligC2 | Consent-Valid Signature | Num | LOGICALNA | 0 | No |
| | | | | | 1 | Yes |
| | | | | | 9 | Not Applicable |

The SAS System

SAS Dataset=SUBJFLOW Dataset Label=Subject Flow

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|-----------------|------|-----------|-------|-------------------|
| | | | | | .A | Not Applicable |
| | | | | | .D | Not Done |
| | | | | | .K | Unknown |
| | | | | | -97 | Not Done |
| | | | | | -98 | Unknown |
| | | | | | -99 | Not Applicable |
| | | | | | | |
| 52 | eligCVD | History-CVD | Num | LOGICALNA | 0 | No |
| | | | | | 1 | Yes |
| | | | | | 9 | Not Applicable |
| | | | | | .A | Not Applicable |
| | | | | | .D | Not Done |
| | | | | | .K | Unknown |
| | | | | | -97 | Not Done |
| | | | | | -98 | Unknown |
| | | | | | -99 | Not Applicable |
| | | | | | | |
| 53 | status | Survival Status | Num | STATUS | 0 | Dead |
| | | | | | 1 | Alive |
| | | | | | 2 | Consent withdrawn |
| | | | | | 3 | Lost to Follow-Up |
| | | | | | .A | Not Applicable |
| | | | | | .D | Not Done |
| | | | | | .K | Not Known |

The SAS System

SAS Dataset=SUBJFLOW Dataset Label=Subject Flow

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|------------------------------|------|----------|-------|--------------------------|
| | | | | | -97 | Not Done |
| | | | | | -98 | Not Known |
| | | | | | -99 | Not Applicable |
| | | | | | | |
| 54 | dateLfu | Date of last followup | Num | DATE | | |
| | | | | | | |
| 55 | willing | Willingness to continue | Num | WILLING | 0 | Yes |
| | | | | | 1 | No-patient refusal |
| | | | | | 2 | No-family requested |
| | | | | | 3 | No-Physician requested |
| | | | | | 4 | No-Cognitive impairment |
| | | | | | 5 | No-Adverse Event |
| | | | | | 6 | No-eligibilty incorrect |
| | | | | | 9 | No-Other |
| | | | | | .A | Not Applicable |
| | | | | | .D | Not Done |
| | | | | | .K | Not Known |
| | | | | | -97 | Not Done |
| | | | | | -98 | Not Known |
| | | | | | -99 | Not Applicable |
| | | | | | | |
| 56 | withdraw | Subsequent Follow-up Allowed | Num | WITHDRAW | 1 | Medical records only |
| | | | | | 2 | No Follow-up Information |
| | | | | | .A | Not Applicable |

The SAS System

SAS Dataset=SUBJFLOW Dataset Label=Subject Flow

| Order | Variable Name | Variable Label | Type | Format | Range | Format Label |
|-------|---------------|----------------|------|--------|-------|----------------|
| | | | | | .D | Not Done |
| | | | | | .K | Not Known |
| | | | | | -97 | Not Done |
| | | | | | -98 | Not Known |
| | | | | | -99 | Not Applicable |
| | | | | | | |