

Project Tree • ADSL_DER •

Program

ADS_DER

Program

Save ▾ Run ▾ Stop | Selected Server: Local | Analyze Program | Export | Send To | Create | Changes Commit History Properties

```

1  /*
2  Developer: Chintan Vajani
3  Date: 08/07/2023
4  Output: Deriving adsl dataset as per specs.
5  */
6
7
8 %supp(dom=DM);  I
9 %supp(dom=DS);
10 %supp(dom=DD);
11
12
13 data adsl;
14 length REGION1 RACEOTH ethnic2 TRT01P TRT01A AGEGR1 AGEGR2 AGEGR3 SFFL SAFFL race2 $200.;
15 set dm(rename=(Sex = Sex_1 RACE = Race_1 ETHNIC = ETHNIC_1 ARM = ARM_1 ARMCD = ARMCD_1 ACTARM = ACTARM_1 ACTARMCD = ACTARMCD_1));
16   if strip(upcase(country)) in ('USA','CAN') then REGION1="North America";
17   else if strip(upcase(country)) in ('BEL','DEU','ESP','FRA','GBR','ITA','NLD') then REGION1="Europe";
18   else REGION1="Rest of World";
19   if strip(upcase(country)) in ('USA','CAN') then REGION1N=1;
20   else if strip(upcase(country)) in('BEL','DEU','ESP','FRA','GBR','ITA','NLD') then REGION1N=2;
21   else REGION1N=3;
22   Sex = strip(Sex_1);
23   if sex = "F" then SEXN = '1';
24   else if sex = "M" then SEXN = '2';
25   RACE = strip(Race_1);
26   /*If race in('','Not reported') then race2=''; 
27   else if race in('WHITE') then race2 = 'White';
28   else race2='Non-white';
29   if race in ('','NOT REPORTED') then race2=''; else if race in ("WHITE") then race2='White';else race2="Non-White";
30 If RACEOTH="ASIAN" then Race3 = "ASIAN";
31 else RACE3 = Race;
32 ETHNIC = strip(Ethnic_1);
33 if ethnic not in ('HISPANIC OR LATINO','NOT HISPANIC OR LATINO',' ') then ETHNIC2='OTHER';
34 else ETHNIC2= ETHNIC;
35 ARM = strip(Arm_1);
36 ARMCD = strip(Armcd_1);
37 ACTARM = strip(ACTARM_1);
38 ACTARMCD = strip(ACTARMCD_1);
39 if armcd = 'SACI' then TRT01P = ARM;
40 else if armcd in ('CAPE', 'ERIB', 'GEMC', 'VINO') then TRT01P = 'Treatment Physician Choice';
41 if ARMcd='SACI' then TRT01PN = '1';
42 else if ARMcd in ('CAPE', 'ERIB', 'GEMC', 'VINO') then TRT01PN = '2';
43 if actarmcd='SACI' then TRT01A = actarm;
44 else if actarmcd in ('CAPE', 'ERIB', 'GEMC', 'VINO') then TRT01A = 'Treatment Physician Choice';
45 if actarmcd='SACI' then TRT01AN = '1';
46 else if actarmcd in ('CAPE', 'ERIB', 'GEMC', 'VINO') then TRT01AN = '2';
47 INFCOND=input((scan(rfidc,1,'T')),??e8601da.);
```

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```

37   ACTARM = strip(ACTARM_1);
38   ACTARMCD = strip(ACTARMCD_1);
39   if armcd = 'SACI' then TRT01P = ARM;
40   else if armcd in ('CAPE', 'ERIB', 'GEMC', 'VINO') then TRT01P = 'Treatment Physician Choice';
41   if ARMcd='SACI' then TRT01PN = '1';
42   else if ARMcd in ('CAPE', 'ERIB', 'GEMC', 'VINO') then TRT01PN = '2';
43   if actarmcd='SACI' then TRT01A = actarm;
44   else if actarmcd in ('CAPE', 'ERIB', 'GEMC', 'VINO') then TRT01A = 'Treatment Physician Choice';
45   if actarmcd='SACI' then TRT01AN = '1';
46   else if actarmcd in ('CAPE', 'ERIB', 'GEMC', 'VINO') then TRT01AN = '2';
47   INFCOND=input((scan(rfidctc,1,'T')),??e8601da.);
48   TRTSDT=input((scan(RFSTDTC,1,'T')),IS8601da.);
49   TRTSTM=input((scan(rfxstdtc,2,'T')),??e8601tm.);
50   format TRTSTM time7. ;
51   if TRTSTM ne . then TRTSDTM=input(rfxstdtc,??e8601dt. );
52   else TRTSDTM=input(cats(rfxstdtc,'T00:00'),??e8601dt. );
53   TRTEDT=input((scan(rfxendtc,1,'T')),??e8601da. );
54   TRTETM=input((scan(rfxendtc,2,'T')),??e8601tm. );
55   if trtetm ne . then TRTEDTM=input(rfxendtc,??e8601dt. );
56   else TRTEDTM=input(cats(rfxendtc,'T00:00'),??e8601dt. );
57   dthdt=input(dthdt,??is8601da. );
58   if RFXENDTC <= DTHDTC <= RFXENDTC+30 then DTH2FL = 'Y';

59
60   if AGE = . then AGEGR1 = 'Missing';
61   else if AGE < 50 then AGEGR1 = '< 50 years';
62   else if AGE >= 50 and age < 65 then AGEGR1 = '50 - 64 years' ;
63   else if AGE >= 65 then AGEGR1 = '>= 65 years';
64   if AGEGR1 = '< 50 years' then AGEGR1N = '1';
65   if AGEGR1 = '50 - 64 years' then AGEGR1N = '2';
66   if AGEGR1 = '>= 65' then AGEGR1N = '3';
67   if AGEGR1 = 'Missing' then AGEGR1N = '4';

68
69   if AGE = . then AGEGR2 = 'Missing';
70   else if AGE < 50 then AGEGR2 = '< 50 years';
71   else if AGE >= 50 then AGEGR2 = '>= 50 years';
72   if AGEGR2 = '< 50 years' then AGEGR2N = '1';
73   if AGEGR2 = '>= 50 years' then AGEGR2N = '2';
74   if AGEGR2 = 'Missing' then AGEGR2N = '3';

75
76   if AGE = . then AGEGR3 = 'Missing';
77   else if AGE < 65 then AGEGR3 = '< 65 years';
78   else if AGE>=65 then AGEGR3 = '>= 65 years';
79   if AGEGR3 = '< 65 years' then AGEGR3N = '1';
80   if AGEGR3 = '>= 65 years' then AGEGR3N = '2';
81   if AGEGR3 = 'Missing' then AGEGR3N = '3';

82
83   if cmmiss(TRTSDT,TRTEDT)=0 then TRTDUR = (TRTEDT - TRTSDT + 1);

```

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Servers

<input checked="" type="checkbox"/> Refresh
<input checked="" type="checkbox"/> Disconnect
<input checked="" type="checkbox"/> Stop
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76      if AGE = . then AGEGR3 = 'Missing';
77      else if AGE < 65 then AGEGR3 = '< 65 years';
78      else if AGE>=65 then AGEGR3 = '>= 65 years';
79      if AGEGR3 = '< 65 years' then AGEGR3N ='1';
80      if AGEGR3 = '>= 65 years' then AGEGR3N = '2';
81      if AGEGR3 = 'Missing' then AGEGR2N = '3';
82
83      if cmiss(TRTSDT,TRTEDT)=0 then TRTDUR = (TRTEDT - TRTSDT + 1);
84      if cmiss(TRTSDT,TRTEDT)=0 then TRTDURW = (TRTEDT - TRTSDT + 1) / 7;
85
86      if ARMCD = 'SCRNFAIL' then SFFL = 'Y';
87      else SFFL = 'N';
88
89
90      IF ^missing(INFCOND) then ENRLFL= 'Y' ;
91      else ENRLFL= 'N';
92
93      if armcd in ('SACI','CAPE', 'ERIB', 'GEMC', 'VINO') then ITTFL ='Y';
94      else ITTFL = 'N';
95
96      If TRTSDT>. then SAFFL= 'Y';
97      else SAFFL = 'N';
98      If DTHDT ne . then lcdt= DTHDT;Else lcdt=input(rfpndtc,IS8601da.);
99      LCDY= LCDT- TRTSDT+ 1;
100     keep STUDYID USUBJID SUBJID SITEID INVNAM RACEOTH AGE COUNTRY ETHNIC ETHNIC2 REGION1 REGION1N Sex SEXN RACE Race2 TRTDUR TRTDURW AGEGR2N lcdt lcdy AGEGR2 RAC
101    run;
102
103  proc sort data=adsl;
104    by studyid usubjid subjid;
105    run;
106
107
108  data eot;
109    set ds;
110    length studyid subjid usubjid dctreas eotstt $200;
111    where DSCAT='DISPOSITION EVENT' and DSSCAT='END OF TREATMENT';
112    eotdt=input(dsstdtc,??e8601da.);
113    DCTREAS= strip(dsdecod);
114    if dsdecod = "PROGRESSIVE DISEASE" then DCTREAS = "Progressive Disease";
115    else if dsdecod = "PROTOCOL DEVIATION (NON-COMPLIANCE)" then DCTREAS = "Protocol Deviation";
116    else if dsdecod = "DEATH" then DCTREAS ="Death";
117    else if dsdecod = "TREATMENT DELAY > 3 WEEKS" then DCTREAS = "Treatment Delay > 3 Weeks";
118    else if dsdecod = "WITHDRAWAL OF CONSENT" then DCTREAS = "Withdrawal of Consent";
119    else if dsdecod = "ADVERSE EVENT" then DCTREAS = "Adverse Event";
120    else if dsdecod = "Pregnancy" then DCTREAS = "Pregnancy";
121    else if dsdecod = "LOST TO FOLLOW-UP" then DCTREAS = "Lost to Follow-Up";
122    else if dsdecod = "COVID-19 " then DCTREAS ="COVID19";

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```

94     else ITTFL = 'N';
95
96     If TRTSDT>. then SAFFL= 'Y';
97     else SAFFL = 'N';
98     If DTHDT ne . then lcdt= DTHDT; Else lcdt=input(rfpPENDTC,IS8601da.);
99     LCDY= LCDT- TRTSDT+ 1;
100    keep STUDYID USUBJID SUBJID SITEID INVNAME RACEOTH AGE COUNTRY ETHNIC ETHNIC2 REGION1 REGION1N Sex SEXN RACE Race2 TRTDUR TRTDURW AGEGR2N lcdt lcdy AGEGR;
101    run;
102
103  proc sort data=adsl;
104    by studyid usubjid subjid;
105    run;
106
107
108  data eot;
109    set ds;
110    length studyid subjid usubjid dctreas eotstt $200;
111    where DSCAT='DISPOSITION EVENT' and DSSCAT='END OF TREATMENT';
112    eotdt=input(dsstdtc,??e8601da.);
113    DCTREAS= strip(dsdecod);
114    if dsdecod = "PROGRESSIVE DISEASE" then DCTREAS = "Progressive Disease";
115    else if dsdecod = "PROTOCOL DEVIATION (NON-COMPLIANCE)" then DCTREAS = "Protocol Deviation";
116    else if dsdecod = "DEATH" then DCTREAS = "Death";
117    else if dsdecod = "TREATMENT DELAY > 3 WEEKS" then DCTREAS = "Treatment Delay > 3 Weeks";
118    else if dsdecod = "WITHDRAWAL OF CONSENT" then DCTREAS = "Withdrawal of Consent";
119    else if dsdecod = "ADVERSE EVENT" then DCTREAS = "Adverse Event";
120    else if dsdecod = "Pregnancy" then DCTREAS = "Pregnancy";
121    else if dsdecod = "LOST TO FOLLOW-UP" then DCTREAS = "Lost to Follow-Up";
122    else if dsdecod = "COVID-19 " then DCTREAS = "COVID19";
123    else if dsdecod = "STUDY DRUG NOT ADMINISTERED (AFTER RANDOMIZATION)" then DCTREAS = "Study Drug Not Administered (after Randomization)";
124    else if dsdecod = "OTHER" then DCTREAS = "Other";
125
126    If EOTDT ne '' then EOTSTT = 'Discontinued From Study Treatment';
127    else EOTSTT = 'Continuing in Treatment';
128    keep studyid subjid usubjid EOTDT DCTREAS EOTSTT;
129    run;
130  proc sort data=eot nodupkey; by studyid usubjid subjid ;run;
131
132
133  data eos;
134    set ds;
135    where DSCAT='DISPOSITION EVENT' & DSSCAT='END OF STUDY';
136    EOSDT = input(dsstdtc,??e8601da.);
137    DCSREAS = strip(DSDECOD);
138    if dsdecod = "COVID-19" then DCSREAS = "COVID19";
139    else if dsdecod = "DEATH" then DCSREAS = "Death";
140    else if dsdecod = "LOST TO FOLLOW-UP" then DCSREAS = "Lost to Follow-Up";

```

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```

127     else EOTSTT = 'Continuing in Treatment';
128     keep studyid subjid usubjid EOTDT DCTREAS EOTSTT;
129   run;
130
131
132
133 data eos;
134   set ds;
135   where DSCAT='DISPOSITION EVENT' & DSSCAT='END OF STUDY';
136   EOSDT = input(dsstdtc,??e8601da.);
137   DCSREAS = strip(DSDECOD);
138   if dsdecod = "COVID-19" then DCSREAS = "COVID19";
139   else if dsdecod = "DEATH" then DCSREAS = "Death";
140   else if dsdecod = "LOST TO FOLLOW-UP" then DCSREAS = "Lost to Follow-Up";
141   else if dsdecod = "OTHER" then DCSREAS = "Other";
142   else if dsdecod = "SPONSOR DECISION" then DCSREAS = "Sponsor Decision";
143   else if dsdecod = "WITHDRAWAL OF CONSENT" then DCSREAS = "Withdrawal of Consent";
144   keep studyid subjid usubjid EOSDT DCSREAS;
145   run;
146
147
148
149
150 data dsdth;
151   set DD;
152   where ddtestcd in ('PRCDTH');
153   DTHREAS=upcase(ddstresc);
154   if DDSTRES = 'OTHER' then dthreaso = propcase(dthcoth);
155   keep DTHREAS DTHREASO studyid subjid usubjid;
156   run;
157
158 proc sort data=dsdth; by studyid usubjid subjid ;run;
159
160 data ddall;
161   set dd;
162   where ddtestcd in ('PRCDTH');
163   DTHREAS=upcase(ddstresc);
164   if DDSTRES = 'OTHER' then dthreaso = propcase(dthcoth);
165   keep DTHREAS DTHREASO studyid subjid usubjid ;
166   run;
167
168 proc sort ;
169   by studyid usubjid subjid;
170   run;
171
172 data DTHAENUM;
173   set dd;
174   where DTHAENUM ne '';
175   keep DTHAENUM studyid subjid usubjid ;
176   run;

```

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```

148
149
150  data dsdth;
151    set DD;
152  where ddtestcd in ('PRCDTH');
153  DTHREAS=upcase(ddstresc);
154  if DDSTRES = 'OTHER' then dthreaso = propcase(dthcoth);
155  keep DTHREAS DTHREASO studyid subjid usubjid;
156  run;
157  proc sort data=dsdth; by studyid usubjid subjid ;run;
158  data ddall;
159    set dd;
160  where ddtestcd in ('PRCDTH');
161  DTHREAS=upcase(ddstresc);
162  if DDSTRES = 'OTHER' then dthreaso = propcase(dthcoth);
163  keep DTHREAS DTHREASO studyid subjid usubjid ;
164  run;
165  proc sort ;
166  by studyid usubjid subjid;
167  run;
168
169  data DTHAENUM;
170    set dd;
171    where DTHAENUM ne '';
172    keep DTHAENUM studyid subjid usubjid ;
173  run;
174  proc sort data=dthaenum nodupkey; by studyid usubjid subjid ; run;
175
176  data first;
177  merge adsl eot eos dsdth DTHAENUM;
178  by studyid usubjid subjid;
179  If EOTDT ne '' then EOTSTT = 'Discontinued From Study Treatment'; else EOTSTT = 'Continuing in Treatment';
180  If safl="N" then eotstt='';
181  run;
182
183
184  data vs;
185  length studyid usubjid vstestcd vsblfl $200;
186  set sdtm.vs(keep=studyid usubjid subjid vstestcd vsblfl vsstresn);
187  where vstestcd in ('HEIGHT','WEIGHT') and vsblfl='Y';
188  run;
189  proc transpose data=vs out=vsall;
190  by studyid usubjid subjid;
191  var vsstresn;
192  id vstestcd;
193  run;
194  data vs_1(keep=studyid usubjid subjid BHEIGHT BWEIGHT BBMI BBSA);

```

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181  run;
182
183
184  data vs;
185  length studyid usubjid vstestcd vsblfl $200;
186  set SDTM.vs(keep=studyid usubjid subjid vstestcd vsblfl vsstresn);
187  where vstestcd in ('HEIGHT','WEIGHT') and vsblfl='Y';
188  run;
189  proc transpose data=vs out=vsall;
190  by studyid usubjid subjid;
191  var vsstresn;
192  id vstestcd;
193  run;
194  data vs_1(keep=studyid usubjid subjid BHEIGHT BWEIGHT BBMI BBSA);
195  set vsall;
196  BHEIGHT = height;
197  BWEIGHT = weight;
198  BBMI =BWEIGHT / ((BHEIGHT/100) ** 2);
199  BBSA=sqrt(Bheight*Bweight/3600);
200  run;
201
202  proc sort data=vs nodupkey; by studyid usubjid subjid ; run;
203  data creatn;
204  length studyid usubjid subjid lbtestcd lbbfl $200;
205  set SDTM.lb(encoding="any");
206  where lbtestcd in ('CREATCLR');
207  bcreatcl=lbstresn;
208  keep studyid usubjid subjid bcreatcl ;
209  run;
210  proc sort data=creatn nodupkey;by studyid usubjid subjid ; run;
211
212  data buracil;
213  length studyid usubjid subjid lbtestcd lbbfl $200;
214  set SDTM.lb(encoding="any");
215  where lbtestcd in ('URACIL') and lbbfl = 'Y';
216  BURACIL=lbstresn;
217  keep studyid usubjid subjid BURACIL ;
218  run;
219
220  proc sort data=BURACIL nodupkey;by studyid usubjid subjid ; run;
221
222
223  data qs;
224  length studyid usubjid qstest qstestcd visit qsstresc $200;
225  set SDTM.qs;
226  where QSTESTCD in('ECOG101') and qsblfl= 'Y';
227  BECOGN = qsstresn;

```

File Edit View Tasks Favorites

Program Tools Help Process Flow

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```
220 proc sort data=BURACIL nodupkey;by studyid usubjid subjid ; run;
221
222
223 data qs;
224   length studyid usubjid qstest qstestcd visit qsstresc $200;
225   set sdtm.qs;
226   where QSTESTCD in('ECOG101') and qsblfl= 'Y';
227   BECOGN = qsstresn;
228   BECOG = cat('Grade ',strip(put(qsstresn,best.)));
229   keep studyid subjid usubjid BECOGN BECOG;
230   run;
231 proc sort data=qs nodupkey; by studyid usubjid subjid ; run;
232
233 data sec;
234   length studyid usubjid qstest qstestcd visit qsstresc SECOG $200;
235   set sdtm.qs;
236   where QSTESTCD in('ECOG101') and upcase(visit)= "SCREENING";
237   SECOGN = QSSTRESN;
238   If SECOGN=0 then SECOG = "0: Normal Activity";
239   else if SECOGN=1 then SECOG= "1: Symptoms but Ambulatory";
240   keep studyid subjid usubjid SECOGN SECOG;
241   run;
242
243 proc sort data=sec nodupkey; by studyid usubjid subjid ; run;
244
245 data is;
246   set sdtm.is;
247   where ITESTCD in ('HBSAG','HCAB') and visit = 'SCREENING';
248   if istestcd = "HBSAG" then do;
249     BHEPB = propcase(ISSTRESC);
250   end;
251   if istestcd = "HCAB" then do;
252     BHEPC = propcase(ISSTRESC);
253   end;
254   keep studyid subjid usubjid BHEPB BHEPC;
255   run;
256 data isall;
257   merge is(where=(BHEPB ne '' ) keep= studyid usubjid subjid BHEPB)
258   is(where=(BHEPC ne '' ) keep= studyid usubjid subjid BHEPC)
259   ;
260   by studyid usubjid subjid ;
261   run;
262 proc sort data=isall nodupkey;
263   by studyid usubjid subjid ;
264   run;
265
266 data lb;
```

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```

259 ;
260 by studyid usubjid subjid ;
261 run;
262 proc sort data=isall nodupkey;
263 by studyid usubjid subjid ;
264 run;
265
266 data lb;
267 length studyid usubjid subjid lbtestcd lbbfl RIMPBAS HIMPBAS $200;
268 set sdm.lb(encoding="any");
269 where lbtestcd in ('CREAT','BILI') and lbbfl = 'Y';
270 if lbtestcd = 'CREAT' then do;
271 if cmiss(lbstresn,lbstnrhi)=0 and lbstresn <= lbstnrhi then do; RIMPBAS = 'Creatinine <=ULN';
272 RIMPBASN = 1;end;
273 else if cmiss(lbstresn,lbstnrhi)=0 and lbstresn >= lbstnrhi then do; RIMPBAS = 'Creatinine >ULN';
274 RIMPBASN = 2;end;
275 else do;RIMPBAS = 'Missing';RIMPBASN= 3;end;
276 end;
277
278 if lbtestcd = 'BILI' then do;
279 if cmiss(lbstresn,lbstnrhi)=0 and lbstresn <= lbstnrhi then do; HIMPBAS = 'Bilirubin <= ULN';
280 HIMPBASN = 1;end;
281 else if cmiss(lbstresn,lbstnrhi)=0 and lbstnrhi < lbstresn <= 1.5*lbstnrhi then do; HIMPBAS = 'ULN < Bilirubin <= 1.5x ULN';
282 HIMPBASN = 2;end;
283 else if cmiss(lbstresn,lbstnrhi)=0 and lbstresn > 1.5*lbstnrhi then do; HIMPBAS = 'Bilirubin > 1.5x ULN';
284 HIMPBASN = 3;end;
285 else do; HIMPBAS="";HIMPBASN = 4;end;
286 end;
287 keep studyid usubjid subjid RIMPBAS RIMPBASN HIMPBAS HIMPBASN;
288 run;
289
290 data lball;
291 merge lb(where=(RIMPBAS ne '')) keep= studyid usubjid subjid RIMPBAS)
292 lb(where=(RIMPBASN ne .) keep= studyid usubjid subjid RIMPBASN)
293 lb(where=(HIMPBAS ne '')) keep= studyid usubjid subjid HIMPBAS)
294 lb(where=(HIMPBASN ne .) keep= studyid usubjid subjid HIMPBASN);
295 if himbas=' ' then do;HIMPBAS='';HIMPBASN=4;end;
296 by studyid usubjid subjid ;
297 run;
298
299 proc sort data=lball nodupkey;
300 by studyid usubjid subjid;
301 run;
302
303 data mis;
304 length T2HSCAT $200;
305 set sdm.mi;

```

Project Tree

- Program
- TBL_14.1.3.1
- Program (2)
- TBL_14.1.13
- Program (3)
- ADAE_DER
- ADEX_DER
- ADRS_DER
- ADSL_DER
- AE_DER
- DS_DER
- EG_DER
- EX_DER
- IE_DER
- IS_DER
- PE_DER
- SV_DER
- VS

Servers

Refresh Disconnect Stop

Servers

Private OLAP Servers

ADSL_DER

Program

Save ▾ Run ▾ Stop Selected Server: Local ▾ Analyze Program ▾ Export ▾ Send To ▾ Create ▾ Changes Commit History Properties

```
295 if himpbas='' then do;HIMPBAS='';HIMPBASN=4;end;
296 by studyid usubjid subjid ;
297 run;
298
299 proc sort data=lball nodupkey;
300 by studyid usubjid subjid;
301 run;
302
303 data mis;
304 length T2HSCAT $200;
305 set sdm.mi;
306 where mitstdtl='H Score of Membrane' and miblfl='Y';
307 T2HS = input(MISTRESC,best12.);
308 if T2HS < 100 then do;
309 T2HSCAT="<100";
310 T2HSCATN=1;
311 end;
312
313 else if 100<=T2HS<=200 then do;
314 T2HSCAT=">=100 and <=200";
315 T2HSCATN=2;end;
316
317 else if T2HS>200 then do;
318 T2HSCAT ">200";
319 T2HSCATN=3;
320 end;
321 keep studyid subjid usubjid T2HS T2HSCAT T2HSCATN miseq;
322 run;
323
324 proc sort data=mis(where=(t2hs ne .)) ;
325 by USUBJID SUBJID miseq;
326 run;
327 proc sort data=mis nodupkey ;
328 by studyid usubjid subjid ;
329 run;
330
331 data rand;
332 set ds;
333 where DSDECOD='RANDOMIZED';
334 randdt=input(dsstdtc,??e860lda.);
335 keep randdt studyid subjid usubjid;
336 run;
337 proc sort nodupkey;
338 by studyid usubjid subjid;
339 run;
340
341 proc sort data=sdtm.cm(encoding="any" where=(cmcat="Subsequent Therapies" and cmstdtc ne '')) out=cm;
```

Project Tree

- Program
- TBL_14.1.3.1
- Program (2)
- TBL_14.1.1.3
- Program (3)
- ADAE_DER
- ADEX_DER
- ADRS_DER
- ADSL_DER
- AE_DER
- DS_DER
- EG_DER
- EX_DER
- IE_DER
- IS_DER
- PE_DER
- SV_DER
- VS

Servers

- Refresh
- Disconnect
- Stop

- Servers
- Private OLAP Servers

ADS1_DER -

Program*

Save ▾ Run ▾ Stop | Selected Server: Local | Analyze Program | Export | Send To | Create | Changes | Commit | History | Properties

```
322 run;
323
324 proc sort data=mis(where=(t2hs ne .)) ;
325   by USUBJID SUBJID misq;
326 run;
327 proc sort data=mis nodupkey ;
328 by studyid usubjid subjid ;
329 run;
330
331 data rand;
332 set ds;
333 where DSDECOD='RANDOMIZED';
334 randdt=input(dsstdtc,??e8601da.);
335 keep randdt studyid subjid usubjid;
336 run;
337 proc sort nodupkey;
338 by studyid usubjid subjid;
339 run;
340
341 proc sort data=sdtm.cm(encoding="any" where=(cmcat="Subsequent Therapies" and cmstdtc ne '')) out=cm;
342 by studyid usubjid subjid cmstdtc;
343 run;
344
345
346 data cm;
347 set cm;
348 by studyid usubjid subjid cmstdtc;
349 if first.subjid;
350 ACANDT = input(cmstdtc,??is8601da.);
351 keep studyid usubjid subjid ACANDT;
352 run;
353
354
355
356 data visliver;
357 set sdtm.tu ;
358 IF tustresc in ('NON-TARGET','TARGET') and (tueval in ('INVESTIGATOR', 'INDEPENDENT ASSESSOR')) and upcase(visit)='SCREENING' and (index(upcase(tuloc),'LIVER')>0 or index(visit,'LIVER')>0);
359 else visliver='N';
360 if visliver='Y';
361 vislivern=1;
362 keep studyid usubjid subjid tustresc tueval visit tuloc VISLIVER VISLIVERn;
363 run;
364 proc sort DATA=visliver nodupkey;
365 by studyid usubjid subjid;
366 run;
367 proc sort data=visliver nodupkey;
368 by studyid usubjid subjid ;
```

File Edit View Tasks Favorites Program Tools Help Process Flow

Project Tree

- Program
 - TBL_14.1.3.1
 - Program (2)
 - Program (3)
 - ADAE_DER
 - ADEX_DER
 - ADRS_DER
 - ADSL_DER
 - AE_DER
 - DS_DER
 - EG_DER
 - EX_DER
 - IE_DER
 - IS_DER
 - PE_DER
 - SV_DER
 - VS

Servers

Refresh Disconnect Stop

- Servers
- Private OLAP Servers

ADSL_DER

Program*

Save ▾ Run ▾ Stop | Selected Server: Local ▾ Analyze Program ▾ Export ▾ Send To ▾ Create ▾ Changes Commit History Properties

```

352 run;
353
354
355
356 data visliver;
357   set sdtm.tu;
358   IF tustresc in ('NON-TARGET','TARGET') and (tueval in ('INVESTIGATOR', 'INDEPENDENT ASSESSOR')) and upcase(visit)='SCREENING' and (index(upcase(tuloc),'LIVER')>0 or index(upcase(tuloc),
359     else visliver='N';
360   if visliver='Y';
361   vislivern=1;
362   keep studyid usubjid subjid tustresc tueval visit tuloc VISLIVER VISLIVERn;
363   run;
364 proc sort DATA=visliver nodupkey;
365   by studyid usubjid subjid;
366   run;
367 proc sort data=visliver nodupkey;
368   by studyid usubjid subjid;
369   run;
370
371 data vislung;
372   set sdtm.tu;
373   if tustresc in ('NON-TARGET','TARGET') and (tueval in ('INVESTIGATOR', 'INDEPENDENT ASSESSOR')) and upcase(visit)='SCREENING' and (index(upcase(tuloc),'LUNG')>0 or index(upcase(tuloc),'P
374   else VISLUNG='N';
375   keep studyid usubjid subjid VISLUNG;
376   run;
377 proc sort data=vislung nodupkey;
378   by studyid usubjid subjid;
379   run;
380
381 data visoth;
382   set sdtm.tu;
383   if tustresc in ('NON-TARGET','TARGET') and (tueval in ('INVESTIGATOR', 'INDEPENDENT ASSESSOR')) and upcase(visit)='SCREENING' and (index(upcase(tuloc),'ADRENAL')>0 or index(upcase(tuloc)
384   else VISOTH='N';
385   keep studyid usubjid subjid VISOTH;
386   run;
387 proc sort data=visoth nodupkey;
388   by studyid usubjid subjid;
389   run;
390
391 data final;
392   merge first vs_1 creatn qs sec isall rand BURACIL lball mis cm visliver(keep= studyid usubjid subjid visliver) vislung visoth;
393   by studyid usubjid subjid;
394   if armcd='SCRNFAIL' then do;
395     BWWEIGHT=.;
396     BBMI=.;
397     BECOG='';
398     BECOGN=.;

```

Project Tree

- Program
- TBL_14.1.3.1
- Program (2)
- TBL_14.1.1.3
- Program (3)
- ADAE_DER
- ADEX_DER
- ADRS_DER
- ADSL_DER
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- EG_DER
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Servers

Refresh Disconnect Stop
 Servers
 Private OLAP Servers

ADSL_DER

Program*
 Save ▾ Run ▾ Stop | Selected Server: Local ▾ Analyze Program ▾ Export ▾ Send To ▾ Create ▾ Changes Commit History Properties

```

385 keep studyid usubjid subjID VISOTH ;
386 run;
387 %proc sort data=visoth nodupkey;
388 by studyid usubjid subjID ;
389 run;
390
391 %data final;
392 merge first vs_1 creatn qs sec isall rand BURACIL lball mis cm visliver(keep= studyid usubjid subjID visliver) vislung visoth;
393 by studyid usubjid subjID ;
394 if armcd='SCRNFAIL' then do;
395 BWEIGHT=.;
396 BBMI=.;
397 BECOG='';
398 BECOGN=.;
399 RIMPPBAS='';
400 RIMPPBASN=.;
401 HIMPPBAS='';
402 HIMPPBASN=.;
403 end;
404 if visliver='' then visliver='N';
405 if VISLUNG='' then VISLUNG='N';
406 if VISOTH='' then VISOTH='N';
407 IF VISLIVER='Y' OR VISLUNG='Y' OR VISOTH='Y' then VISMETA='Y'; else VISMETA='N';
408 IF .< BCREATCL<30 then creatcat= '< 30mL/min';
409 else if 30< BCREATCL<60 then creatcat= '30 -60 mL/min';
410 else if BCREATCL>=60 then creatcat= '>=60 mL/min';
411 dthreas=strip(put(dthreas,Sdthreas.));if Dthfl ne 'Y' and dthreas='Missing' then dthreas='';
412 if ENRLFL='' then ENRLFL='N';
413 ADDDOMAIN = 'ADSL';
414 format INFCONDNT TRTSDT TRTEDT DTHDT EOTDT EOSDT LCDT acandt randdt date9.
415 TRTSDTM TRTEDTM datetime20.
416 TRTSTM TRTESTM TIME8. ;
417
418 if himpbas='' then do;HIMPPBAS='Missing';HIMPPBASN=4;end;
419 if RIMPPBAS='' then do;RIMPPBAS='Missing';RIMPPBASN=3;end;
420
421 if nmiss(lcdt,randdt)=0 then fupdur=((lcdt-randdt)+1)/30.4375;
422 run;
423
424 %data prod;
425 set adam.adsl(encoding="any" keep=STUDYID
426 USUBJID
427 SUBJID
428 SITEID
429 INVNAM
430 COUNTRY
431 REGION1

```