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NOTE: SAS (r) Proprietary Software 9.3 (TS1M1)
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NOTE: This session is executing on the X64_ES08R2  platform.

NOTE: Updated analytical products:

SAS/STAT 9.3_M1

NOTE: SAS initialization used:
      real time           2.35 seconds
      cpu time            1.23 seconds

1
2     ****************************************************
3     ** finlstat: TOMUS final analysis dataset
4     ****************************************************;
5     option nofmterr noSYMBOLGEN noMLOGIC;
6
7     %let cut='13SEP2010'd;   * Event cutoff date;
8
9     libname matchfl  "\\Neri1\PROJECTS3\UITN\Protocol #3_TOMUS\Datasets\Public Use_NIDDK
Reposity\datasets";
NOTE: Libref MATCHFL was successfully assigned as follows:
      Engine:        V9
      Physical Name: \\Neri1\PROJECTS3\UITN\Protocol #3_TOMUS\Datasets\Public Use_NIDDK
Reposity\datasets
10    libname urtmbl  "\\Neri1\PROJECTS3\UITN\Protocol_AcrossStudies\DataSets\09_0715\raw";
NOTE: Libref URTMBL was successfully assigned as follows:
      Engine:        V9
      Physical Name: \\Neri1\PROJECTS3\UITN\Protocol_AcrossStudies\DataSets\09_0715\raw
11    libname utmbl  "\\Neri1\PROJECTS3\UITN\Protocol #3_TOMUS\DataSets\09_0715";
NOTE: Libref UTMBL was successfully assigned as follows:
      Engine:        V9
      Physical Name: \\Neri1\PROJECTS3\UITN\Protocol #3_TOMUS\DataSets\09_0715
12    libname u_tm  "\\Neri1\PROJECTS3\UITN\Protocol #3_TOMUS\DataSets\Current";
NOTE: Libref U_TM was successfully assigned as follows:
      Engine:        V9
      Physical Name: \\Neri1\PROJECTS3\UITN\Protocol #3_TOMUS\DataSets\Current
13    libname u_tm2  "\\Neri1\PROJECTS3\UITN\Protocol #3_TOMUS\DataSets\10_1012";
NOTE: Libref U_TM2 was successfully assigned as follows:
      Engine:        V9
      Physical Name: \\Neri1\PROJECTS3\UITN\Protocol #3_TOMUS\DataSets\10_1012
14    libname ur  "\\Neri1\PROJECTS3\UITN\Protocol_AcrossStudies\DataSets\Current\raw";
NOTE: Libref UR was successfully assigned as follows:
      Engine:        V9
      Physical Name: \\Neri1\PROJECTS3\UITN\Protocol_AcrossStudies\DataSets\Current\raw
15
16    proc format;
17    value assign  1='Retropubic'
18                  2='Transobturator';
NOTE: Format ASSIGN has been output.
19    value yna  0='No'
20               1='Yes';
NOTE: Format YNA has been output.
21    value ynb  1='Yes'
22               2='No';
NOTE: Format YNB has been output.
23    value sex  1='Female';
NOTE: Format SEX has been output.
24    value racea 1='White'
25                2='Black'
26                3='Asian'
27                4='Pacific Island'
28                5='American Indian'
29                6='Other'
30                7='Multi race';
NOTE: Format RACEA has been output.
31    value raceb 1='White'
32                2='Black'
33                3='Asian'
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34              4='Pacific Island'
35              5='American Indian'
36              99='Other';
NOTE: Format RACEB has been output.
37   value hispa 1='Hispanic'
38              2='Non-hispanic White'
39              3='Non-hispanic Black'
40              4='Non-hispanic Other';
NOTE: Format HISPA has been output.
41   value npcat 0='0'
42              1='1-2'
43              2='3-4'
44              3='>=5';
NOTE: Format NPCAT has been output.
45   value menoa 1='PRE-MENOPAUSAL'
46              2='POST-MENOPAUSAL'
47              3='SOMEWHERE IN-BETWEEN'
48              4='NOT SURE';
NOTE: Format MENOA has been output.
49   value ahrt 0='No'
50              1='Yes'
51              2='Pre';
NOTE: Format AHRT has been output.
52   value bmiab 0='<30'
53              1='>=30';
NOTE: Format BMIAB has been output.
54   value udiform 0='Not at all bothersome'
55               1='Slightly bothersome'
56               2='Moderately bothersome'
57               3='Greatly bothersome';
NOTE: Format UDIFORM has been output.
58   value sfa  0='Never'
59              1='Seldom'
60              2='Sometimes'
61              3='Usually'
62              4='Always';
NOTE: Format SFA has been output.
63   value sfb  4='Never'
64              3='Seldom'
65              2='Sometimes'
66              1='Usually'
67              0='Always';
NOTE: Format SFB has been output.
68   value sfc  4='Much more intense'
69              3='More intense     '
70              2='Same intensity   '
71              1='Less intense     '
72              0='Much less intense';
NOTE: Format SFC has been output.
73   value del  1='1'
74              2='2'
75              3='3'
76              4='4+';
NOTE: Format DEL has been output.
77   value stcat 1='0,1'
78              2='2'
79              3='3,4';
NOTE: Format STCAT has been output.
80   value npre  0='0'
81              1='1'
82              2='2'
83              3='3'
84              4='4'
85              5='5'
86              6='6'
87              7='7'
88              8='8+';
NOTE: Format NPRE has been output.
89   value csec 1='Cesarean delivery only         '
90              2='Vaginal/Cesarean delivery      '
91              3='Neither/No delivery            ';
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NOTE: Format CSEC has been output.
92   value aac 1='Aa [-3,-2]  '
93            2='Aa (-2,-1]  '
94            3='Aa (-1,max] ';
NOTE: Format AAC has been output.
95   value strmix 1='stress only         '
96               2='stress predominant  '
97               3='mixed               ';
NOTE: Format STRMIX has been output.
98   value smkst  0='No         '
99               1='Former     '
100              2='Current    ';
NOTE: Format SMKST has been output.
101  value obes  1='<25          '
102              2='25-30        '
103              3='>=30         ';
NOTE: Format OBES has been output.
104  value pcdurf           . = 'missing'
105                   0-.999999 = '<1'
106                         1-3 = '[1,3]'
107             3.00000001-100 = '>3';
NOTE: Format PCDURF has been output.
108  value health 1="1: Excellent" 2="2:Very good" 3="3: Good" 4="4:Fair" 5="5:Poor";
NOTE: Format HEALTH has been output.
109  value flpatt 1='Continuous, smooth      '
110              2='Continuous, fluctuating'
111              3='Intermittent            ';
NOTE: Format FLPATT has been output.
112  value leakm 1='Yes'
113              2='No'
114              3='NA, VLPPs obtained at or prior to MCC';
NOTE: Format LEAKM has been output.
115  value pfsvd 1='Pure or predominant detrusor'
116              2='Pure or predominant abdominal'
117              3='Mixed'
118              4='Indeterminate / uninterpretable';
NOTE: Format PFSVD has been output.
119  value lk_grpf -1 = '-1:Protocol violation'
120                0 = 'Invalid or implausible'
121                1 = '1:Patient leaked w/ unreduced Valsalva'
122                2 = '2:Patient leaked w/ reduced Valsalva only'
123                3 = '3:Patient leaked w/ cough at MCC only'
124                4 = '4:Patient did not leak';
NOTE: Format LK_GRPF has been output.
125  value usilk   0 = 'leak_grp=4'
126               1 = 'leak_grp in (1,2,3)';
NOTE: Format USILK has been output.
127  value ltstatf 1="1:Cont"
128               2="2:Lost"
129               3="3:Failed";
NOTE: Format LTSTATF has been output.
130  value trtm_01f 1 = "1: RMUS"
131                0 = "0: TMUS";
NOTE: Format TRTM_01F has been output.
132  value vlpp90f 0="0: <= 90"
133               1="1: > 90";
NOTE: Format VLPP90F has been output.
134  value vlpp3f 1="0: <=90"
135              2="1: > 90"
136              3="missing";
NOTE: Format VLPP3F has been output.
137  value assigf 1="1:RMUS" 2="2:TMUS";
NOTE: Format ASSIGF has been output.
138  value trtm_01nf 1="1:TMUS" 0="0: RMUS";
NOTE: Format TRTM_01NF has been output.
139  value failnf 1="1:success" 0="0:failure";
NOTE: Format FAILNF has been output.
140  value failnfb 1="1:failure" 2="2:success";
NOTE: Format FAILNFB has been output.
141  value failnfc 1="1:failure" 0="0:success";
NOTE: Format FAILNFC has been output.
```

```
142   value msgvlppf 1="1:missing" 0="0:not missing";
NOTE: Format MSGVLPPF has been output.
143   run;

NOTE: PROCEDURE FORMAT used (Total process time):
      real time           0.06 seconds
      cpu time            0.06 seconds


144
145   proc sort data=utmbl.rand_tmus out=randa;by master_id;run;

NOTE: There were 597 observations read from the data set UTMBL.RAND_TMUS.
NOTE: The data set WORK.RANDA has 597 observations and 18 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.03 seconds
      cpu time            0.03 seconds


146   proc sort data=urtmbl.f305 out=f305; by master_id visit; run;

NOTE: There were 1087 observations read from the data set URTMBL.F305.
NOTE: The data set WORK.F305 has 1087 observations and 86 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.06 seconds
      cpu time            0.03 seconds


147   proc sort data=matchfl.tm_aid out=tmaid; by master_id; run;

NOTE: Input data set is already sorted; it has been copied to the output data set.
NOTE: There were 597 observations read from the data set MATCHFL.TM_AID.
NOTE: The data set WORK.TMAID has 597 observations and 11 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


148
149   *** Puts run date in SAS log;
150   data _null_;
151     rundate=date(); runtime=time();
152     put rundate=date8. runtime=time.;
153   run;

rundate=27NOV13 runtime=10:35:28
NOTE: DATA statement used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


154
155  data failures;
156  set u_tm2.failuresfromf394;
157
158  if master_id = "172000167" then do;
159   vd_fail = 2; pad_fail = 2; objfail = 2; subjfail = 2; anyfail = 2;
160  end;
161  if master_id = "142000200" then do;
162   vd_fail = 2; subjfail = 2; anyfail = 2;
163  end;
164  if master_id = "121000819" then do;
165   mesa_fail = 2; subjfail = 2; anyfail = 2;
166  end;
167  if master_id = "151000414" then do;
168   mesa_fail = 2; subjfail = 2; anyfail = 2;
169  end;
170
171  drop site site_a subsite site_id;
172  run;
```

```
NOTE: There were 597 observations read from the data set U_TM2.FAILURESFROMF394.
NOTE: The data set WORK.FAILURES has 597 observations and 162 variables.
NOTE: DATA statement used (Total process time):
      real time           0.21 seconds
      cpu time            0.14 seconds


173
174  data death;
175  set ur.f395;
176  run;

NOTE: Format X739F was not found or could not be loaded.
NOTE: Format X739F was not found or could not be loaded.
NOTE: There were 6 observations read from the data set UR.F395.
NOTE: The data set WORK.DEATH has 6 observations and 13 variables.
NOTE: DATA statement used (Total process time):
      real time           0.01 seconds
      cpu time            0.00 seconds


177
178  data baseline;
179  set utmbl.baseline_tm;
180  run;
NOTE: There were 597 observations read from the data set UTMBL.BASELINE_TM.
NOTE: The data set WORK.BASELINE has 597 observations and 470 variables.
NOTE: DATA statement used (Total process time):
      real time           0.73 seconds
      cpu time            0.37 seconds


181
182  *also need surgeon information;
183  data f310;
184  set u_tm2.f310;
185  run;

NOTE: There were 597 observations read from the data set U_TM2.F310.
NOTE: The data set WORK.F310 has 597 observations and 82 variables.
NOTE: DATA statement used (Total process time):
      real time           0.17 seconds
      cpu time            0.14 seconds


186
187  data uds;
188  set utmbl.baseline_uds;
189  vlpp90 = .;
190  if . < vlpp_nored <= 90 then vlpp90 = 0;
191  else if vlpp_nored > 90 then vlpp90 = 1;
192  vlpp3 = .;
193  if . < vlpp_nored <= 90 then vlpp3 = 1;
194  else if vlpp_nored > 90 then vlpp3 = 2;
195  else if vlpp_nored = . then vlpp3 = 3;
196  vlpp5 = .;
197
198  keep master_id vlpp_nored vlpp90 vlpp3 mucp_w leak_grp usi usinoinvalid;
199  format vlpp90 vlpp90f. vlpp3 vlpp3f.;
200  run;

NOTE: There were 595 observations read from the data set UTMBL.BASELINE_UDS.
NOTE: The data set WORK.UDS has 595 observations and 8 variables.
NOTE: DATA statement used (Total process time):
      real time           0.23 seconds
      cpu time            0.15 seconds


201
202  proc sort data=death; by master_id;
```

```
NOTE: There were 6 observations read from the data set WORK.DEATH.
NOTE: The data set WORK.DEATH has 6 observations and 13 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


203  proc sort data=failures; by master_id;

NOTE: There were 597 observations read from the data set WORK.FAILURES.
NOTE: The data set WORK.FAILURES has 597 observations and 162 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.03 seconds
      cpu time            0.03 seconds


204  proc sort data=f310; by master_id;

NOTE: There were 597 observations read from the data set WORK.F310.
NOTE: The data set WORK.F310 has 597 observations and 82 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


205  proc sort data=uds; by master_id;
206

NOTE: There were 595 observations read from the data set WORK.UDS.
NOTE: The data set WORK.UDS has 595 observations and 8 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


207  data finlstat;
208  merge failures(in=a) death(in=b) f310(in=c) uds(in=d);
209  by master_id;
210  if a;
211
212  *if a woman has an obj failure report, then status is obj failure;
213  *presumably any obj failure report pre-dated date of death;
214  *days of observation = days between randomization and first obj failure;
215  if objfail = 1 then do;
216      obj_status = 3;
217      obj_days = objfail_d - rando_dt;
218  end;
219  *if died and no other failure;
220  *days of obs = days btwn rando and death;
221  *HL 11/10/2010 - comment out the section on deaths and just treat as lost-to-followup;
222  *until they failed (in which case they are in failures);
223  /*
224  else if final_status = 5 and objfail = 2 then do;
225      *status = 2;
226      *redo - censoring women at death;
227      obj_status = 1;
228      obj_days = death_d - rando_dt;
229  end;
230  */
231  *if no failure and no death but lost;
232  *days of obs = days btwn rando and date of last visit prior to loss;
233  *HL 4/16/2010;
234  *only set to lost if lost before 24 month visit;
235  *HL 8/13/2010 - modify to include TF12 also;
236  *note: there were no losts at TF24;
237  else if final_status in (2,3,4,5,6) and objfail = 2 and last_visit in
("TF2W","TF6W","TF06","TF12") then do;
238      obj_status = 2;
239      obj_days = obsdays;
240  end;
241  *all others are continuing;
```

```
242  *days of obs = days btwn rando and cut date;
243  *****************************************************************;
244  *NOTE: the obj_days should actually be cut to be at 24 month visit;
245  else do;
246      obj_status = 1;
247      obj_days = &cut - rando_dt;
248  end;
249  *end portion on obj failure;
250
251  *HL - issue here with obj_days;
252  *WHEN PERFORM KAPLAN-MEIER ANALYSIS, MAY NEED TO ADDRESS THE OBJ_DAYS ISSUE,
253  *SINCE TIME COULD BE MUCH MORE THAN 24 MONTH VISIT;
254  *think this actually is simply a limitation of the data;
255  *we know when exactly people fail, but not exactly when they succeed;
256  *this matches how the SISTEr analysis was done;
257
258  *now add in the portion for subjective failure;
259  *if a woman has an subj failure report, then status is subj failure;
260  *presumably any subj failure report pre-dated date of death;
261  *days of observation = days between randomization and first subj failure;
262  if subjfail = 1 then do;
263      subj_status = 3;
264      subj_days = subjfail_d - rando_dt;
265  end;
266  *if died and no other subj failure;
267  *days of obs = days btwn rando and death;
268  *HL 11/10/2010 - delete death section;
269  /*
270  else if final_status = 5 and subjfail = 2 then do;
271      *status = 2;
272      *redo - censoring women at death;
273      subj_status = 1;
274      subj_days = death_d - rando_dt;
275  end;
276  */
277  *if no subj failure and no death but lost;
278  *days of obs = days btwn rando and date of last visit prior to loss;
279  *HL 4/16/2010;
280  *only set to lost if lost before 12 month visit;
281  *HL 8/13/2010 - add TF12;
282  else if final_status in (2,3,4,5,6) and subjfail = 2 and last_visit in
("TF2W","TF6W","TF06","TF12") then do;
283      subj_status = 2;
284      subj_days = obsdays;
285  end;
286  *all others are continuing;
287  *days of obs = days btwn rando and cut date;
288  *****************************************************************;
289  *NOTE: the subj_days should actually be cut to be at 12 month visit;
290  else do;
291      subj_status = 1;
292      subj_days = &cut - rando_dt;
293  end;
294  *end portion on subj failure;
295
296  *now add in the portion for any Obj and subj failure;
297  *if a woman has a failure report, then status is failure;
298  *presumably any failure report pre-dated date of death;
299  *days of observation = days between randomization and first failure;
300  if anyfail = 1 then do;
301      any_status = 3;
302      any_days = anyfail_d - rando_dt;
303  end;
304  *if died and no other failure;
305  *days of obs = days btwn rando and death;
306  *HL 11/10/2010 - delete death section;
307  /*
308  else if final_status = 5 and anyfail = 2 then do;
309      any_status = 1;
310      any_days = death_d - rando_dt;
311  end;
```

```
312  */
313  *if no failure and no death but lost;
314  *days of obs = days btwn rando and date of last visit prior to loss;
315  *HL 4/16/2010;
316  *only set to lost if lost before 12 month visit;
317  *HL 8/13/2010 - update with TF12;
318  else if final_status in (2,3,4,5,6) and anyfail = 2 and last_visit in
("TF2W","TF6W","TF06","TF12") then do;
319      any_status = 2;
320      any_days = obsdays;
321  end;
322  *all others are continuing;
323  *days of obs = days btwn rando and cut date;
324  else do;
325      any_status = 1;
326      any_days = &cut - rando_dt;
327  end;
328  *end portion on obj and subj failure;
329
330  *HL 9/30/2009 - UPDATED;
331  *now add in the portion for stress failure (as in SISTER);
332  *if a woman has a failure report, then status is failure;
333  *presumably any failure report pre-dated date of death;
334  *days of observation = days between randomization and first failure;
335  *HL 8/16/2010 - found a typo with stressdays, not stress_days;
336  if stressfail = 1 then do;
337      stress_status = 3;
338      stress_days = stressfail_d - rando_dt;
339  end;
340  *if died and no other failure;
341  *days of obs = days btwn rando and death;
342  *HL 11/10/2010 delete death section;
343  /*
344  else if final_status = 5 and stressfail = 2 then do;
345      stress_status = 1;
346      stress_days = death_d - rando_dt;
347  end;
348  */
349  *if no failure and no death but lost;
350  *days of obs = days btwn rando and date of last visit prior to loss;
351  *HL 4/16/2010;
352  *only set to lost if lost before 12 month visit;
353  *HL 8/13/2010 - update with TF12;
354  else if final_status in (2,3,4,5,6) and stressfail = 2 and last_visit in
("TF2W","TF6W","TF06","TF12") then do;
355      stress_status = 2;
356      stress_days = obsdays;
357  end;
358  *all others are continuing;
359  *days of obs = days btwn rando and cut date;
360  else do;
361      stress_status = 1;
362      stress_days = &cut - rando_dt;
363  end;
364  *end portion on stress failure;
365
366
367  *HL - 7/31/2009;
368  *information about cases that should not be included in the PP analysis;
369  *obtained from MM;
370  inelig = 2;
371  if master_id in ('111000012','131000069','131000252','131000956','131000752',
372  '142000335','151000572',
373  '172000101','172000156','191000123','191000407') then inelig = 1;
374  *updated deaths as of 8/13/2010;
375  death = 2;
376  if master_id in ('111000227','112000285','131000138','131000194','181000257') then death =
1;
377  crossover = 2;
378  if master_id in ('151000334','191000407') then crossover = 1;
379  nostudyproc = 2;
```

```
380   if master_id in ('141000300','181000100') then nostudyproc = 1;
381
382   *8/13/2010 - will need to update;
383   *although never used below in analysis;
384
385   *this assumes that anyone other than those who failed, was a success;
386   *e.g. lost to follow-up were successes;
387   objfail_01 = .;
388   if objfail = 2 then objfail_01 = 0;
389   else if objfail = 1 then objfail_01 = objfail;
390
391   subjfail_01 = .;
392   if subjfail = 2 then subjfail_01 = 0;
393   else if subjfail = 1 then subjfail_01 = subjfail;
394
395   *HL 9/14/2009;
396   anyfail_01 = .;
397   if anyfail = 2 then anyfail_01 = 0;
398   else if anyfail = 1 then anyfail_01 = anyfail;
399
400   *HL 9/30/2009;
401   stressfail_01 = .;
402   if stressfail = 2 then stressfail_01 = 0;
403   else if stressfail = 1 then stressfail_01 = stressfail;
404
405   *HL 9/10/2010;
406   etmfail_01 = .;
407   if etmfail = 2 then etmfail_01 = 0;
408   else if etmfail = 1 then etmfail_01 = etmfail;
409
410   trtm_01 = .;
411   if assignment = 2 then trtm_01 = 0;
412   else if assignment = 1 then trtm_01 = assignment;
413
414   *updated 8/16/2010;
415   *create discrete time points;
416   *for objective failure;
417   *note: for 12 month analysis, used 242 days (182 + 60) for designation between 6 and 12
months;
418   *NOTE: 8/20/2010 - even if change to 450, 510 days, still will have an issue with the
denominator unless do extensive
418!  checking;
419   *so, think it makes sense to report <=425 days, same as SISTEr - 365 days + 60 day grace
period;
420   if objfail_01 = 1 then do;
421       obj_visit = 0;
422       if . < obj_days <= 242 then obj_visit = 6;
423       else if 242 < obj_days <= 425 then obj_visit = 12; *HL - 8/20/2010 - needs to be 450 to
match 12 month analysis;
424       else if obj_days > 425 then obj_visit = 24;
425   end;
426   else if objfail_01 = 0 then do;
427       obj_visit = 0;
428       if . < obj_days <= 242 then obj_visit = 6;
429       else if 242 < obj_days <= 425 then obj_visit = 12;
430       else if obj_days > 425 then obj_visit = 24;
431   end;
432
433   *for subjective failure;
434   if subjfail_01 = 1 then do;
435       subj_visit = 0;
436       if . < subj_days <= 242 then subj_visit = 6;
437       *else if master_id = "121000740" then subj_visit = 24; *HL - one exception - not
recorded at 12 months;
438       else if 242 < subj_days <= 425 then subj_visit = 12; *HL - 8/20/2010 - needs to be 510
to match 12 month analysis;
439       else if subj_days > 425 then subj_visit = 24;
440   end;
441   else if subjfail_01 = 0 then do;
442       subj_visit = 0;
443       if . < subj_days <= 242 then subj_visit = 6;
```

```
444      else if 242 < subj_days <= 425 then subj_visit = 12;
445      else if subj_days > 425 then subj_visit = 24;
446  end;
447
448  *HL 9/14/2009;
449  *for any failure;
450  if anyfail_01 = 1 then do;
451      any_visit = 0;
452      if . < any_days <= 242 then any_visit = 6;
453      *else if master_id = "121000740" then subj_visit = 24; *HL - one exception - not
recorded at 12 months;
454      else if 242 < any_days <= 425 then any_visit = 12; *HL - 8/20/2010 - needs to be 510? to
match 12 month analysis;
455      else if any_days > 425 then any_visit = 24;
456  end;
457  else if anyfail_01 = 0 then do;
458      any_visit = 0;
459      if . < any_days <= 242 then any_visit = 6;
460      else if 242 < any_days <= 425  then any_visit = 12;
461      else if any_days > 425 then any_visit = 24;
462  end;
463
464  *HL 9/30/2009;
465  *for stress failure;
466  if stressfail_01 = 1 then do;
467      stress_visit = 0;
468      if . < stress_days <= 242 then stress_visit = 6;
469      else if 242 < stress_days <= 425 then stress_visit = 12;
470      else if stress_days > 425 then stress_visit = 24;
471  end;
472  else if stressfail_01 = 0 then do;
473      stress_visit = 0;
474      if . < stress_days <= 242 then stress_visit = 6;
475      else if 242 < stress_days <= 425 then stress_visit = 12;
476      else if stress_days > 425 then stress_visit = 24;
477  end;
478
479  *create variable for pp;
480  perprotocol = 1;
481  if inelig = 1 or crossover = 1 or nostudyproc = 1 then perprotocol = 0;
482
483  *HL 8/17/2010 - change coding for sensitivity variables from 0/1 to 1/2 to match objfail;
484
485  *HL 9/3/2009;
486  *create variables for sensitivity analysis;
487  *set all lost-to-fu to failures;
488  obj_sens_fail = .;
489  if obj_status = 2 then obj_sens_fail = 1;
490  else if obj_status = 3 then obj_sens_fail = 1;
491  else if obj_status = 1 then obj_sens_fail = 2;
492
493  *set all lost-to-fu to failures;
494  subj_sens_fail = .;
495  if subj_status = 2 then subj_sens_fail = 1;
496  else if subj_status = 3 then subj_sens_fail = 1;
497  else if subj_status = 1 then subj_sens_fail = 2;
498
499  *HL 9/14/2009;
500  any_sens_fail = .;
501  if any_status = 2 then any_sens_fail = 1;
502  else if any_status = 3 then any_sens_fail = 1;
503  else if any_status = 1 then any_sens_fail = 2;
504
505  *HL 9/30/2009;
506  stress_sens_fail = .;
507  if stress_status = 2 then stress_sens_fail = 1;
508  else if stress_status = 3 then stress_sens_fail = 1;
509  else if stress_status = 1 then stress_sens_fail = 2;
510
511  *HL 11/16/2009;
512  trtm_01n = .;
```

```
513  if trtm_01 = 1 then trtm_01n = 0;
514  else if trtm_01 = 0 then trtm_01n = 1;
515  objfail_01n = .;
516  if objfail_01 = 0 then objfail_01n = 1;
517  else if objfail_01 = 1 then objfail_01n = 0;
518  subjfail_01n = .;
519  if subjfail_01 = 0 then subjfail_01n = 1;
520  else if subjfail_01 = 1 then subjfail_01n = 0;
521  etmfail_01n = .;
522  if etmfail_01 = 0 then etmfail_01n = 1;
523  else if etmfail_01 = 1 then etmfail_01n = 0;
524  msgvlpp = .;
525  if vlpp_nored = . then msgvlpp = 1;
526  else if vlpp_nored ne . then msgvlpp = 0;
527  newvlpp = .;
528  if vlpp_nored = . then newvlpp = 118.86;
529  else if vlpp_nored ne . then newvlpp = vlpp_nored;
530  newvlppmax = .;
531  if vlpp_nored = . then newvlppmax = 266;
532  else if vlpp_nored ne . then newvlppmax = vlpp_nored;
533
534  *HL 11/16/2009 - to correctly calculate type of failure;
535  *set all missings to no;
536  if st_fail = . then st_failt = 2;
537  else if st_fail ne . then st_failt = st_fail;
538  if pad_fail = . then pad_failt = 2;
539  else if pad_fail ne . then pad_failt = pad_fail;
540  if retrm_fail = . then retrm_failt = 2;
541  else if retrm_fail ne . then retrm_failt = retrm_fail;
542  if mesa_fail = . then mesa_failt = 2;
543  else if mesa_fail ne . then mesa_failt = mesa_fail;
544  if vd_fail = . then vd_failt = 2;
545  else if vd_fail ne . then vd_failt = vd_fail;
546
547  label
548  st_failt = "st_fail with missing set to no"
549  pad_failt = "pad_fail with missing set to no"
550  retrm_failt = "retrm_fail with missing set to no"
551  mesa_failt = "mesa_fail with missing set to no"
552  vd_failt = "vd_fail with missing set to no"
553  trtm_01n = "1=TMUS, 0=RMUS"
554  objfail_01n = "objfail with 0 = fail, 1 = success"
555  subjfail_01n = "subjfail with 0 = fail, 1 = success"
556  etmfail_01n = "etmfail with 0 = fail, 1 = success"
557  msgvlpp = "indicator for if vlpp missing"
558  newvlpp = "set missing vlpp to mean value - 118.86"
559  newvlppmax = "set missing vlpp to max value - 266"
560  obj_sens_fail = "objfail with 2 = success, 1 = failure with lost-to-fu set to fail"
561  subj_sens_fail = "subjfail with 2 = success, 1 = failure with lost-to-fu set to fail"
562  any_sens_fail = "anyfail with 2 = success, 1 = failure with lost-to-fu set to fail"
563  stress_sens_fail = "stressfail with 2 = success, 1 = failure with lost-to-fu set to fail"
564  obj_visit = "visit at which objectively failed or censored"
565  subj_visit = "visit at which subjectively failed or censored"
566  any_visit = "visit at which any failed or censored"
567  stress_visit = "visit at which stress failed or censored"
568  trtm_01 = "assignment with 1 = RMUS, 0 = TMUS"
569  objfail_01 = "objfail with 0 = success, 1 = failure"
570  subjfail_01 = "subjfail with 0 = success, 1 = failure"
571  etmfail_01 = "etmfail with 0 = success, 1 = failure"
572  anyfail_01 = "anyfail with 0 = success, 1 = failure"
573  stressfail_01 = "stressfail with 0 = success, 1 = failure"
574  inelig = "ineligible per MM"
575  death = "death per MM"
576  crossover = "crossover per MM"
577  nostudyproc ="did not receive study procedure per MM"
578  anyfail_d ="date of first failure - obj or subj"
579  f394_comp_d ="f394 completion date"
580  any_status = "first obj or subj failure"
581  any_days = "days to first obj or subj failure"
582  anyfail_d = "date of first any failure"
583  stress_status = "first stress failure"
```

```
584  stress_days = "days to first stress failure"
585  stressfail_d = "date of first stress failure"
586  obj_status = "first objective failure"
587  obj_days = "days to first objective failure"
588  objfail_d ="date of first obj failure"
589  retrm_d ="date of first retreatment failure"
590  retrm_fail = "retreatment failure - surgery, medical, behav, device or other"
591  site = "clinical site"
592  subjfail_d = "date of first subj failure"
593  subj_status = "first subj failure"
594  subj_days = "days to first subj failure";
595
596  drop has310 i rand_days;
597  run;

NOTE: Character values have been converted to numeric values at the places given by:
(Line):(Column).
     411:4   412:9   412:39
NOTE: There were 597 observations read from the data set WORK.FAILURES.
NOTE: There were 6 observations read from the data set WORK.DEATH.
NOTE: There were 597 observations read from the data set WORK.F310.
NOTE: There were 595 observations read from the data set WORK.UDS.
NOTE: The data set WORK.FINLSTAT has 597 observations and 213 variables.
NOTE: DATA statement used (Total process time):
     real time           0.49 seconds
     cpu time            0.43 seconds


598
599  **************************************;
600  *ANALYSIS PP;
601  **************************************;
602
603  **************************************;
604  *analyze PP (exclude ineligible pts, no study procedure and crossovers);
605  *count deaths in analysis - censored at death;
606  /*
607  data pp;
608  set finlstat;
609  if perprotocol = 0 then delete;
610  run;
611  */;
612
613  data tomusfinal;
614    merge tmaid finlstat;
615    by master_id;
616
617    drop master_id st_fail_d mesa_fail_d pad_fail_d vd_fail_d surg_fail_d med_fail_d
618      behav_fail_d devic_fail_d other_fail_d retrm_d COMP_BY
619      st_fail mesa_fail pad_fail vd_fail surg_fail med_fail behav_fail device_fail other_fail
620      FAIL_ASSOC FAIL_VISIT OTHR_FAIL_SP PI_SIG PI_INIT PI_SIG_D FORMSTAT_ID DESTATUS PRIOR_06
621      visit f394_comp_d COMP_D LAST_VISIT FINAL_STATUS ADMIN_SPEC LOST_D DOC_FU_1 DOC_FU_2
DOC_FU_3
622      CONS_WDRAW WDRAW_D ADMIN_D ADD_COMM CONT_TREAT date dropout GRP_SITE_ID CONSENT_D
BIRTHDATE
623      rando_dt CONFIRMATION_NO BLINDED_ID TMUS_RETREAT E_CONSENT E_CONS_D REP_BLOOD_CONS_D
ETOM_ENROLL
624      ETOM_ENROLL_D UDS_SITE_ID REP_URINE_CONS_D F34R_U_COLL_D F32R_B_COLL_D REP_MANUAL_ENTRY
625      obsdate objfail_d subjfail_d etmfail_d anyfail_d stressfail_d SURG_DATE comp_d_310
WHICH_SURG
626      PRIM_SURG P_SURG_INIT OTH_SURG UT_LIG_SUS SAC_LIG_SUS ILI_SUS ANT_COL VAG_PAR_REP
ST_POST_COL
627      DEF_POST_REP POST_REP VAG_HYST OOPH DIFF_SURG DIFF_SURG_SP OP_INC_F OP_INC_L SLING_INC_F
SLING_INC_L
628      GEN_ANES SPIN_ANES EPI_ANES SED_ANES LOC_ANES L_ANES_OB L_ANES_AB L_ANES_VAG MED_NAME
MED_EPI ANTI_PRIOR
629      ANTI_ADM_T ADDL_DOSE ADDL_DOSE_SP RETRO_HYDRO EBL_CASE EBL_SLING PI_VASO D_PRESSURE
PACKING SUTURE
630      INC_EXTENDED I_EXT_DESC BLOOD_TRANS NUM_AUT NUM_NONAUT VAG_EPI_PERF CYST_RESULTS
BLAD_PER BP_LOC_LAT
631      BP_LOC_DOME BP_LOC_TRIG BP_TROCAR BP_TRO_DES URETH_PER UP_TROCAR UP_TROCAR_D AE_SURG
```

```
SURG_SIG SURG_SIG_D
632      BL_OTHER BL_OTHER_DES EVENT_NUM EVENT_CODE CODE99_SPEC RS_ID RS_ORDER DEATH_D DEATH_T
CAUSE SOURCE
633      PROC_RELATE NARRATIVE rand_days SITE_ID site assignment randyrmo;
634
635      label sitename = "Site";
636      label perprotocol = "perprotocol with 1=yes, 0=no";
637      label etmfail = "etmfail with 1 = fail, 2 = success";
638      label vlpp90 = "1 = vlpp_nored > 90 vs. 0 = no";
639      label vlpp3 = "3 categories VLPP";
640
641
642  format trtm_01n trtm_01nf.;
643  format objfail_01n subjfail_01n etmfail_01n failnf.;
644  format msgvlpp msgvlppf.;
645
646  *format inelig death crossover nostudyproc perprotocol yesnof.;
647
648  format obj_status any_status subj_status stress_status ltstatf. ;
649  format retrm_fail retropubic concomsx usi usinoinvalid perprotocol yna.;
650  format inelig death crossover nostudyproc
651          st_failt pad_failt retrm_failt mesa_failt vd_failt ynb.;
652
653  format objfail subjfail etmfail anyfail stressfail obj_sens_fail subj_sens_fail
any_sens_fail stress_sens_fail failnfb.;
654
655  format objfail_01 subjfail_01 anyfail_01 stressfail_01 etmfail_01 failnfc.;
656
657  format trtm_01 trtm_01f.;
658
659  run;

NOTE: There were 597 observations read from the data set WORK.TMAID.
NOTE: There were 597 observations read from the data set WORK.FINLSTAT.
NOTE: The data set WORK.TOMUSFINAL has 597 observations and 66 variables.
NOTE: DATA statement used (Total process time):
      real time           0.23 seconds
      cpu time            0.14 seconds
```