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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           2.34 seconds
      cpu time            1.18 seconds

1
2    ************************************************
3    ** tomusm12_uds: TOMUS M12 UDS dataset
4    ************************************************;
5    option nofmterr noSYMBOLGEN noMLOGIC;
6
7    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
8    libname rawtom  "\\Neri1\PROJECTS3\UITN\Protocol_AcrossStudies\Datasets\Current\Raw";
NOTE: Libref RAWTOM was successfully assigned as follows:
      Engine:        V9
      Physical Name: \\Neri1\PROJECTS3\UITN\Protocol_AcrossStudies\Datasets\Current\Raw
9    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
10
11   proc format;
12   value assign  1='Retropubic'
13                 2='Transobturator';
NOTE: Format ASSIGN has been output.
14   value yna  0='No'
15                 1='Yes';
NOTE: Format YNA has been output.
16   value ynb  1='Yes'
17                2='No';
NOTE: Format YNB has been output.
18   value sex  1='Female';
NOTE: Format SEX has been output.
19   value racea 1='White'
20               2='Black'
21               3='Asian'
22               4='Pacific Island'
23               5='American Indian'
24               6='Other'
25               7='Multi race';
NOTE: Format RACEA has been output.
26   value raceb 1='White'
27               2='Black'
28               3='Asian'
29               4='Pacific Island'
30               5='American Indian'
31               99='Other';
NOTE: Format RACEB has been output.
32   value hispa 1='Hispanic'
33               2='Non-hispanic White'
34               3='Non-hispanic Black'
35               4='Non-hispanic Other';
NOTE: Format HISPA has been output.
36   value npcat 0='0'
37               1='1-2'
38               2='3-4'
39               3='>=5';
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NOTE: Format NPCAT has been output.
40   value menoa 1='PRE-MENOPAUSAL'
41               2='POST-MENOPAUSAL'
42               3='SOMEWHERE IN-BETWEEN'
43               4='NOT SURE';
NOTE: Format MENOA has been output.
44   value ahrt 0='No'
45              1='Yes'
46              2='Pre';
NOTE: Format AHRT has been output.
47   value bmiab 0='<30'
48               1='>=30';
NOTE: Format BMIAB has been output.
49   value udiform 0='Not at all bothersome'
50                 1='Slightly bothersome'
51                 2='Moderately bothersome'
52                 3='Greatly bothersome';
NOTE: Format UDIFORM has been output.
53   value sfa  0='Never'
54              1='Seldom'
55              2='Sometimes'
56              3='Usually'
57              4='Always';
NOTE: Format SFA has been output.
58   value sfb  4='Never'
59              3='Seldom'
60              2='Sometimes'
61              1='Usually'
62              0='Always';
NOTE: Format SFB has been output.
63   value sfc  4='Much more intense'
64              3='More intense     '
65              2='Same intensity   '
66              1='Less intense     '
67              0='Much less intense';
NOTE: Format SFC has been output.
68   value del  1='1'
69              2='2'
70              3='3'
71              4='4+';
NOTE: Format DEL has been output.
72   value stcat 1='0,1'
73               2='2'
74               3='3,4';
NOTE: Format STCAT has been output.
75   value npre  0='0'
76               1='1'
77               2='2'
78               3='3'
79               4='4'
80               5='5'
81               6='6'
82               7='7'
83               8='8+';
NOTE: Format NPRE has been output.
84   value csec 1='Cesarean delivery only         '
85              2='Vaginal/Cesarean delivery      '
86              3='Neither/No delivery            ';
NOTE: Format CSEC has been output.
87   value aac 1='Aa [-3,-2]  '
88            2='Aa (-2,-1]  '
89            3='Aa (-1,max] ';
NOTE: Format AAC has been output.
90   value strmix 1='stress only         '
91                2='stress predominant  '
92                3='mixed               ';
NOTE: Format STRMIX has been output.
93   value smkst  0='No          '
94                1='Former      '
95                2='Current     ';
NOTE: Format SMKST has been output.
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96   value obes  1='<25          '
97               2='25-30        '
98               3='>=30         ';
NOTE: Format OBES has been output.
99   value pcdurf          . = 'missing'
100                   0-.999999 = '<1'
101                         1-3 = '[1,3]'
102              3.00000001-100 = '>3';
NOTE: Format PCDURF has been output.
103  value health 1="1: Excellent" 2="2:Very good" 3="3: Good" 4="4:Fair" 5="5:Poor";
NOTE: Format HEALTH has been output.
104  value flpatt 1='Continuous, smooth     '
105               2='Continuous, fluctuating'
106               3='Intermittent           ';
NOTE: Format FLPATT has been output.
107  value leakm 1='Yes'
108              2='No'
109              3='NA, VLPPs obtained at or prior to MCC';
NOTE: Format LEAKM has been output.
110  value pfsvd 1='Pure or predominant detrusor'
111              2='Pure or predominant abdominal'
112              3='Mixed'
113              4='Indeterminate / uninterpretable';
NOTE: Format PFSVD has been output.
114  value lk_grpf -1 = '-1:Protocol violation'
115                 0 = 'Invalid or implausible'
116                 1 = '1:Patient leaked w/ unreduced Valsalva'
117                 2 = '2:Patient leaked w/ reduced Valsalva only'
118                 3 = '3:Patient leaked w/ cough at MCC only'
119                 4 = '4:Patient did not leak';
NOTE: Format LK_GRPF has been output.
120  value usilk    0 = 'leak_grp=4'
121                 1 = 'leak_grp in (1,2,3)';
NOTE: Format USILK has been output.
122  value ltstatf 1="1:Cont"
123               2="2:Lost"
124               3="3:Failed";
NOTE: Format LTSTATF has been output.
125  value trtm_01f 1 = "1: RMUS"
126                 0 = "0: TMUS";
NOTE: Format TRTM_01F has been output.
127  value vlpp90f 0="0: <= 90"
128                1="1: > 90";
NOTE: Format VLPP90F has been output.
129  value vlpp3f 1="0: <=90"
130              2="1: > 90"
131              3="missing";
NOTE: Format VLPP3F has been output.
132  value assigf 1="1:RMUS" 2="2:TMUS";
NOTE: Format ASSIGF has been output.
133  value trtm_01nf 1="1:TMUS" 0="0: RMUS";
NOTE: Format TRTM_01NF has been output.
134  value failnf 1="1:success" 0="0:failure";
NOTE: Format FAILNF has been output.
135  value failnfb 1="1:failure" 2="2:success";
NOTE: Format FAILNFB has been output.
136  value failnfc 1="1:failure" 0="0:success";
NOTE: Format FAILNFC has been output.
137  value msgvlppf 1="1:missing" 0="0:not missing";
NOTE: Format MSGVLPPF has been output.
138  run;

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


139
140  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.
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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


141  proc sort data=rawtom.f305 out=f305; by master_id visit; run;

NOTE: There were 1118 observations read from the data set RAWTOM.F305.
NOTE: The data set WORK.F305 has 1118 observations and 86 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.06 seconds
      cpu time            0.03 seconds


142  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


143
144  *-------------Focus on followup---------------------------;
145  data f305a0;
146     merge randa (in=rand keep=master_id rando_dt)
147           f305 (in=a where=(visit='TF12' ));
148     by master_id;
149     if a and rand;
150     if rand then rand1=1;
151     if a  then inf305=1;
152     label rand1='1:randomized';
153
NOTE: There were 597 observations read from the data set WORK.RANDA.
NOTE: There were 499 observations read from the data set WORK.F305.
      WHERE visit='TF12';
NOTE: The data set WORK.F305A0 has 499 observations and 89 variables.
NOTE: DATA statement used (Total process time):
      real time           0.24 seconds
      cpu time            0.10 seconds


154  proc sort data=f305a0; by master_id visit; run;

NOTE: There were 499 observations read from the data set WORK.F305A0.
NOTE: The data set WORK.F305A0 has 499 observations and 89 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


155
156  data f305a1;
157      set f305a0;
158
159  *** recode pdet_bl_cmg so that unless pves_bl_cmg and pabd_bl_cmg are missing,
160      then pdet_blcmg_sk is a valid negative number, not a special value***;
161      if pves_bl_cmg >0 and  pabd_bl_cmg >0 then do;
162        pdet_bl_cmg_ck=pves_bl_cmg-pabd_bl_cmg; end;
163   label pdet_bl_cmg_ck = "F305:computed to check D9.pdet_bl_cmg_ck=pves_bl_cmg-pabd_bl_cmg";
164
165  *** recode pabd_bl_pfs so that unless pves_bl_pfs is skipped and pabd_bl_pfs = -2,
166      then pabd_pfsbl_sk is a valid negative number, not a special value;
167
168      if pves_bl_pfs>0 and  pabd_bl_pfs>0 then do;
169        pdet_bl_pfs_ck= pves_bl_pfs - pabd_bl_pfs;end;
170    label pdet_bl_pfs_ck = "F305:computed to check E16c:pdet_bl_pfs_ck= pves_bl_pfs - and
pabd_bl_pfs";
```

```
171
172  ***Check duplicate based on ID and visit;
173   by master_id visit;
174    dup=( (first.visit ^= last.visit) or
175          (first.visit=0 and last.visit=0) );
176  run;
NOTE: There were 499 observations read from the data set WORK.F305A0.
NOTE: The data set WORK.F305A1 has 499 observations and 92 variables.
NOTE: DATA statement used (Total process time):
      real time           0.15 seconds
      cpu time            0.10 seconds


177
178
179  data f305a2; set f305a1;
180    if inf305=1 and rand1=1;
181
182   ** Recode B section;
183     if nif_void_vol>=150 then voil_vol_150=1; else voil_vol_150=2;
184
185
186
187      if nif_max_fl <0  then max_fl_nif = .;  else max_fl_nif = nif_max_fl;
188      if nif_mean_fl <0 then mean_fl_nif = .; else mean_fl_nif = nif_mean_fl;
189      if nif_pattern <0 then pattern_nif = .; else pattern_nif = nif_pattern;
190      if nif_flow_t <0  then flow_t_nif = .;  else flow_t_nif = nif_flow_t;
191      if nif_void_vol<0 then void_vol_nif =.; else void_vol_nif = nif_void_vol;
192      if nif_pvr  <0    then pvr_nif = .;     else pvr_nif = nif_pvr;
193
194      label
195          void_vol_nif="F305:B0.Is voided volume (B4) at least 150 ml?"
196          max_fl_nif = "F305:B1.NIF max flow"
197          mean_fl_nif = "F305:B2.NIF mean flow"
198          pattern_nif = "F305:B6.NIF flow pattern"
199          flow_t_nif = "F305:B3.NIF time to max flow"
200          void_vol_nif = "F305:B4.NIF voided volume"
201          pvr_nif = "F305:B5. NIF post-void residual";
202
203   *-------------------------------------------------------------------------------------;
204   ** Recode C section;
205    if mucp_valid>0 then valid_mucp=mucp_valid;
206
207    ** according C1a(description), Heather decided to make following change;
208    **we dont know whether or not to change in ADEPT;
209    if master_id in ("111000307" "172000281" "173000114")
210                then valid_mucp=1;
211
212    *****create new variables and set some C2--C7 to missing based on UDS group discusion***;
213    *****we dont know whether or not to change in ADEPT;
214    if mucp_li>50 then do; mucp_li=.;mucp_wi=.;end;
215    if mucp_l2>50 then do; mucp_l2=.;mucp_w2=.;end;
216    if mucp_l3>50 then do; mucp_l3=.;mucp_w3=.;end;
217
218    if mucp_wi>0 then mucpwi=mucp_wi;
219    if mucp_w2>0 then mucpw2=mucp_w2;
220    if mucp_w3>0 then mucpw3=mucp_w3;
221
222    if mucp_li>0 then mucpli=mucp_li;
223    if mucp_l2>0 then mucpl2=mucp_l2;
224    if mucp_l3>0 then mucpl3=mucp_l3;
225  /*
226    if master_id in ("131000354" "142000039" "151000174") then do;
227       mucpwi=.;mucpw2=.; mucpw3=.;mucpli=.;mucpl2=.;mucpl3=.;end;
228
229    if master_id in ("131000592" "191000407" "181000097" "181000257" "191000452")
230       then do; mucpwi=.;mucpli=.;end;
231
232    if master_id in ("131000423" "171000052" )then do; mucpw2=.;mucpl2=.;end;
233
234    if master_id in ("112000014" "191000441" "191000623") then do; mucpw3=.;mucpl3=.;end; */
```

```
235
236
237    **compute mean of mucp_w and mucp_l given there are at least two valid value of three***;
238      * MUCP: mean of all three MUCP, if available
239          if only 2 are available, take the mean of those two
240          otherwise, set to missing;
241
242    if (mucpwi^=. and mucpw2^=.) or (mucpwi^=. and mucpw3^=.) or (mucpw2^=. and mucpw3^=.)
243       then do; mucP_w=mean(mucpwi,mucpw2,mucpw3);end;
244
245    if (mucpli^=. and mucpl2^=.) or (mucpli^=. and mucpl3^=.) or (mucpl2^=. and mucpl3^=.)
246       then do;   mucP_l=mean(mucpli,mucpl2,mucpl3); end;
247
248    ** indicator for MUCP which has at least two valid values;
249    if (mucpwi^=. and mucpw2^=.) or (mucpwi^=. and mucpw3^=.) or (mucpw2^=. and mucpw3^=.)
250       then mucp_2valid=1;
251       else if mucpwi=. and mucpw2=. and mucpw3=. then mucp_2valid=2;
252       else mucp_2valid=2;
253
254    ** indicator for FUL which has at least two valid values;
255    if (mucpli^=. and mucpl2^=.) or (mucpli^=. and mucpl3^=.) or (mucpl2^=. and mucpl3^=.)
256       then FUL_2valid=1;
257       else if mucpli=. and mucpl2=. and mucpl3=. then FUL_2valid=2;
258       else FUL_2valid=2;
259
260
261    *format mucp_2valid FUL_2valid  yesnof.;
262    label
263        valid_mucp="F35Q:C1.are all mucp data valid"
264        mucpwi = "F305:C2 if mucp_wi>0"
265        mucpw2 = "F305:C4 if mucp_w2>0"
266        mucpw3 = "F305:C6 if mucp_w3>0"
267        mucp_2valid="=1:at least two valid values of MUCP"
268
269        mucpli = "F305:C3 if mucp_Li>0"
270        mucpl2 = "F305:C5 if mucp_L2>0"
271        mucpl3 = "F305:C7 if mucp_L3>0"
272        mucP_w= "mean(mucpwi,mucpw2,mucpw3)"
273        mucP_L= "mean(mucpLI,mucpL2,mucpL3)"
274        FUL_2valid="=1:at least two valid values of FUL";
275   *-------------------------------------------------------------------------------------;
276   ** Recode D section:CMG;
277
278      if any_invl_cmg>0 then cmg_any_invl = any_invl_cmg;
279      if pves_bl_cmg <0 then pves_base_cmg = .; else pves_base_cmg = pves_bl_cmg;
280      if pabd_bl_cmg <0 then pabd_base_cmg = .; else pabd_base_cmg = pabd_bl_cmg;
281
282
283      *D9 recalculated, and will be used to analysis after discuss with Heather,same as
SISTEr;
284      pdet_base_cmg=pves_base_cmg-pabd_base_cmg;
285      /*if pdet_base_cmg<-5 then pdet_base_cmg=.;*/
286
287      if val_leak>0 then leak_val=val_leak;
288      if lpp_volume>0 then volume_lpp= lpp_volume;
289
290      if first_des >0 then first_desire = first_des;
291      if strong_des >0 then strong_desire = strong_des;
292      if lpp_leak_1>0 then  lpp_leak1=lpp_leak_1;
293      if lpp_leak_2>0 then  lpp_leak2=lpp_leak_2;
294      if lpp_leak_3>0 then  lpp_leak3=lpp_leak_3;
295
296      if mcc_leak>0 then leak_mcc = mcc_leak;
297
298      if mcc <0 then vol_mcc = .; else vol_mcc = mcc;
299      if pves_mcc >0  then mcc_pves = pves_mcc;
300      if pabd_mcc >0  then mcc_pabd = pabd_mcc;
301
302      if det_over>0 then detrusor = det_over;
303
304      if det_1 >0   then detrusor_1 = det_1;
```

```
305      if det_leak_1>0 then detrusor_leak_1 = det_leak_1;
306
307      if det_2>0   then detrusor_2 = det_2;
308      if det_leak_2>0 then detrusor_leak_2 = det_leak_2;
309
310      if det_3 >0   then detrusor_3 = det_3;
311      if det_leak_3>0 then detrusor_leak_3 = det_leak_3;
312
313
314    *****inconsistency of D1--D5 and D6 on randomized IDs(no in followup)*****;
315    *****According UDS group and heather,the following IDs (some other waiting for query back)
316         with D6=1 will be set D7--D9,D13a--D13c and D15a D15b to missing,
317         we dont know whether or not to change in ADEPT;
318    *****depend on queries;
319   /*
320    if master_id in ("151000447" "161000142" "161000357" "161000460") then do;
321         pves_base_cmg=.;
322         pabd_base_cmg=.;
323         pdet_base_cmg=.;
324         lpp_leak1=.;
325         lpp_leak2=.;
326         lpp_leak3=.;
327         mcc_pves=.;
328         mcc_pabd=.;end;
329   */
330      *created mcc_pdet:D15a-D15b;
331       mcc_pdet = mcc_pves - mcc_pabd;
332
333   **updated by liyuan 1/22/09;
334    if leak_val=2 then do;
335         volume_lpp=.;
336         lpp_leak1=.;
337         lpp_leak2=.;
338         lpp_leak3=.;
339     end;
340
341
342      label
343           cmg_any_invl = "F305:D6.FMCP Any invalid conditions for CMG?"
344           pves_base_cmg = "F305:D7.Pves at CMG followup"
345           pabd_base_cmg = "F305:D8.Pabd at CMG followup"
346           pdet_base_cmg = "F305:D9.Pdet at CMG followup"
347           first_desire = "F305:D10.Volume at first desire"
348           strong_desire = "F305:D11.Volume at strong desire"
349           leak_val="F305:D12. Did leakage occur with valsalva"
350           volume_lpp="F305:D13. At what volume"
351           lpp_leak1= "F305:D13a. raw pves at 1st leakage"
352           lpp_leak2= "F305:D13b. raw pves at 2nd leakage"
353           lpp_leak3= "F305:D13c. raw pves at 3rd leakage"
354           leak_mcc ="F305:D14.if mcc_leak>0 then leak_mcc = mcc_leak"
355           vol_mcc  ="F305:D15. Bladder volume at MCC"
356           mcc_pves="F305:D15a. pves at MCC"
357           mcc_pabd="F305:D15b. pabd at MCC"
358           detrusor = "F305:D16.Detrusor overactivity?"
359           detrusor_1 = "F305:D16a.Vol at DO occurence 1"
360           detrusor_leak_1 = "F305:D16a1.Leaking at DO occurence 1?"
361           detrusor_2 = "F305:D16b.Vol at DO occurence 2"
362           detrusor_leak_2 = "F305:D16b1.Leaking at DO occurence 2?"
363           detrusor_3 = "F305:D16c.Vol at DO occurence 3"
364           detrusor_leak_3 = "F305:D16c1.Leaking at DO occurence 3?"
365           mcc_pdet="F305:D15a-D15b:mcc_pves - mcc_pabd";
366
367    *-------------------------------------------------------------------------------------;
368
369    ** Recode E section:PFS;
370    ** there is no inconsistency of E1--E11 and E12 on randomized IDs for followup;
371    ** and these variables have not been used, so have not recoded;
372
373
374      if any_invl_pfs>0 then pfs_any_invl = any_invl_pfs;
375      if pfs_refill>0   then refill_pfs=pfs_refill;
```

```
    if pfs_precough>0 then cough_vd_pfs = pfs_precough;
    if pfs_concord>0  then pves_pabd_cn=pfs_concord;
    if pves_bl_pfs >0 then pfs_pves_bl = pves_bl_pfs;
    if pabd_bl_pfs >0 then pfs_pabd_bl = pabd_bl_pfs;


    *E16c recalculated, and will be used to analysis after discuss with Heather;
     pfs_pdet_bl=pfs_pves_bl -pfs_pabd_bl;

    ** need be confirmed: use the computed value>-5,confirmed;
     if pfs_pdet_bl =<-5 then pfs_pdet_bl = .;

    if pves_qmax<0 then pves_qmax = .;
    if pabd_qmax<0 then pabd_qmax = .;

    **create pdet_qmax;
     pdet_qmax=pves_qmax-pabd_qmax;

    if pfs_max_fl >0  then max_fl_pfs = pfs_max_fl;
    if pfs_flow_t >0  then flow_t_pfs = pfs_flow_t;
    if pfs_void_vol>0 then void_vol_pfs = pfs_void_vol;


    if pfs_void_pat>0 then void_mech = pfs_void_pat;

    if pfs_poscough>0 then cghpstvd_pfs =pfs_poscough;
    if pves_fun_c>0   then pstcgh_pves = pves_fun_c;
    if pabd_fun_c>0   then pstcgh_pabd=pabd_fun_c;

    label
         pfs_any_invl = "F305:E12.Any invalid conditions for PFS?"
         refill_pfs   = "F305:E13.Was the patient refilled for this PFS"
         cough_vd_pfs = "F305:E14.Patient cough before PFS void?"
         pves_pabd_cn = "F305:E15.70% concordance at post-void cough?"
         pfs_pves_bl = "F305:E16a.Pves at PFS followup"
         pfs_pabd_bl = "F305:E16b.Pabd at PFS followup"
         pfs_pdet_bl = "F305:E16c.Pdet at PFS followup"
     /*  pves_qmax = "F305:E17a.Pves at Qmax"
         pabd_qmax = "F305:E17b.Pabd at Qmax" */
         pdet_qmax ="F305:E17a-E17b:pdet at Qmax"
         max_fl_pfs = "F305:E18. Max flow rate"
         flow_t_pfs = "F305:E19.Time to max Flow"
         void_vol_pfs = "F305:E20.Voided Volume"
         void_mech = "F305:E21.PFS voiding patterm"
         cghpstvd_pfs ="F305:E22. Patient cough after PFS void"
         pstcgh_pves = "F305:E23 Pves signal functioning?"
         pstcgh_pabd = "F305:E24 Pabd signal functioning?";
*-------------------------------------------------------------------------------------;
**CMG:define validity and plausibility criteria;
    *<<<<validity>>>>.
         **CMG:creates second validity criterion:valid_cmg;
         *if reviewer determines CMG is invalid (Form CP), or pves or pabd at followup
          is less than 0, then CMG is defined as invalid => exclude all CMG pressure values
          from analysis;

         if cmg_any_invl=1 or pves_base_cmg< 0 or pabd_base_cmg<0 then valid_cmg=0;*invalid;
                                                                  else valid_cmg = 1;*valid;
         label valid_cmg="CMG:second validity criterion: if NOT E6=1 or E16a<0 or E16b<0";

    *<<<<1st plausibility>>>>.;

         **CMG plausibility first criteria: plaus_cmg;
         *if pdet at CMG followup not between -5 and 10, then drop all CMG pressure values
          other than followup ;

         if valid_cmg=0 then plaus_cmg=0;else plaus_cmg=(-5 le pdet_base_cmg le 10);
          * = 1 if CMG is plausible;
          *HL - note: plaus_cmg should be used as the first criteria for deciding if PFS
                     pressure values were valid;

         label plaus_cmg="CMG plausibility first criteria";
```

```
447
448      *<<<<2nd(a) plausibility>>>>;
449
450          *CMG plausibility second criteria (part a):pos_mcc;
451          *if pdet at mcc < -5 then drop all MCC pressure values;
452          *look at plausibility of MCC pressures in 2 steps: neg and rel to PFS BL;
453
454          if plaus_cmg=0 then pos_mcc=0;else pos_mcc=(mcc_pdet ge -5);
455            * = 1,if pdet at MCC is plausible;
456          label pos_mcc="CMG plausibility second criteria (part a)";
457
458       *<<<<2nd(b) plausibility>>>>;
459
460          *CMG plausibility second criteria (part b):plaus_mcc_pfs;
461          *pdet at PFS followup - pdet at MCC < -15 => drop all MCC pressure values;
462
463          if plaus_cmg=0 then plaus_mcc_pfs=0;    else if pfs_pdet_bl<-5 then plaus_mcc_pfs=1;
464           *MODIFICATION 3/20/2006:if pdet at PFS BL out of range, don't compare;
465          else plaus_mcc_pfs = (mcc_pdet - pfs_pdet_bl le 15);
466          Label plaus_mcc_pfs="CMG plausibility second criteria (part b)";
467
468          *for overall plausibility - for now keep it as not considering number 2 part b;
469          * MODIFICATION 7/25/2006: change MCC plausibility criteria: no comparision to
470          PFS followup;
471
472          plaus_mcc = pos_mcc;
473          *plaus_mcc = pos_mcc * plaus_mcc_pfs;*MCC pressures plausible if both criteria met;
474
475          label plaus_mcc="does patient meet all  plausibility criteria of CMG?";
476          *format valid_cmg plaus_cmg pos_mcc plaus_mcc_pfs plausible.
477                   plaus_mcc plaus.;;
478
479          *CMG pressure values: Essentially, D7, D8 and D9 should be based on those with
valid_cmg = yes
480          and don't have to be based on plaus_mcc = yes., D13a, D13b, D13c, D15a, D15b were
considered
481          plausible if there were no invalid conditions for CMG in the validity section above
482          and there were no implausible conditions as per plausibility criteria 1 and 2a
above.
483
484
485   *-------------------------------------------------------------------------------------------;
486   **PFS: define validity and plausibility criteria
487       <<<<1>>>>;
488          **PFS:creates second validity criterion:valid_pfs;
489          **if the reviewer determined there were invalid conditions for the PFS or
490            Pves or Pabd at followup was less than 0 then PFS is invalid;
491          **based on E12,and E16a,E16b;
492          if pfs_any_invl = 1 or pfs_pves_bl < 0 or pfs_pabd_bl < 0 then valid_pfs = 0;
493            else valid_pfs = 1;
494          label valid_pfs="PFS:second validity criterion: if NOT E12=1 or E16a<0 or E16b<0";
495
496      *<<<<2>>>>;
497          **PFS plausibility first criteria: plaus_base_pfs;
498          **(pdet at PFS followup - pdet at MCC)>15 => drop all PFS pressure values
499            pdet at PFS followup < -5 => drop all PFS pressure values;
500          **based on E16a--E16c;
501
502          if valid_pfs = 0 then plaus_base_pfs = 0;
503            else plaus_base_pfs = (pfs_pdet_bl ge -5);    * = 1 if PFS is plausible;
504          label plaus_base_pfs="PFS 1st plausibility criterion";
505
506      *<<<<3>>>>;
507          **PFS plausibility second criteria: plaus_pfs_mcc;
508          **based on D15a,D15b,and E16a--E16c;
509
510           if valid_pfs = 0 then plaus_pfs_mcc = 0; else if mcc_pdet lt -5
511              then plaus_pfs_mcc= 0;*if pdet at MCC out of range, don't compare;
512              else plaus_pfs_mcc=(pfs_pdet_bl-mcc_pdet le 15);* = 1 if PFS is plausible;
513
514           label plaus_pfs_mcc="PFS:second plausibility criterion";
```

```
515
516     *<<<<4>>>>;
517         **PFS:third plausibility criterion:plaus_cough_pfs;
518         **if reviewer indicated there was not 70% concordance,
519           pfs is implausible and exclude all PFS pressure values;
520         if valid_pfs = 0 or pves_pabd_cn = 2 then plaus_cough_pfs = 0;
521             else plaus_cough_pfs = 1;
522
523         label plaus_cough_pfs="PFS:third plausibility criterion";
524
525     *<<<<5>>>>;
526         ** does patient meet all 3 plausibility criteria?;
527          plaus_pfs = plaus_base_pfs * plaus_pfs_mcc * plaus_cough_pfs;
528
529         label plaus_pfs="does patient meet all 3 plausibility criteria of PFS?";
530
531
532     *HL - need to add in this variable to account for the CMG invalid values;
533         if plaus_cmg = 0 or valid_pfs = 0 or plaus_pfs = 0 then press_pfs = 0;
534             else press_pfs = 1;                                          *analyzable;
535
536         label press_pfs="criteria for PFS(E16 and E17)";
537
538         *format plaus_base_pfs plaus_pfs_mcc plaus_cough_pfs plausible.
539                plaus_pfs plaus.;
540
541     **then calculate values in E16 and E17 based only on patients who
542       met press_pfs=1;
543
544
545 *-------------------------------------------------------------------------------------;
546       ********set the variables that do not meet criteria to missing********;
547         **B section;
548         if voil_vol_150=2 then do;
549               max_fl_nif=.;
550               mean_fl_nif=.;
551               flow_t_nif=.;
552               void_vol_nif=.;
553               pvr_nif=.;
554               pattern_nif=.;end;
555
556         **C section;
557          If mucp_2valid=2 or FUL_2valid=2 then do;
558               mucP_w=.;
559               mucP_l=.;end;
560
561         **D section;
562               *HL - change cmg_any_invl=1 to also include valid_cmg ~= 1;
563          If cmg_any_invl=1 or valid_cmg~=1 then do;
564               pves_base_cmg=.;
565               pabd_base_cmg=.;
566               pdet_base_cmg=.;end;
567          if leak_val~=1 then do;
568               volume_lpp=.;end;
569          if cmg_any_invl=1 or leak_val~=1 then do;
570               lpp_leak1=.; lpp_leak2=.; lpp_leak3=.;
571               vlpp_nored=.; lppmin=.; lppmax=.; end;
572
573          If cmg_any_invl=1 then do;
574               mcc_pves=.; mcc_pabd=.;mcc_pdet=.; end;
575
576          if detrusor~=1 then do;
577               detrusor_1=.;  detrusor_leak_1=.;
578               detrusor_2=.;  detrusor_leak_2=.;
579               detrusor_3=.;  detrusor_leak_3=.;
580               detrusor_mean=.;  detrusormin=.;  detrusormax=.; end;
581
582           *CMG Criteria:;
583               *HL - take out D7, D8, D9;
584               *CMG pressure values in  D13a, D13b, D13c, D15a, D15b were
585                considered plausible if there were no invalid conditions for CMG in
```

```
               the validity section above and there were no implausible conditions as
               per plausibility criteria 1 and 2a above;


         if plaus_mcc~=1 then do;
              *HL take out pves_base_cmg, pabd_base_cmg, pdet_base_cmg;
              lpp_leak1=.; lpp_leak2=.; lpp_leak3=.; mcc_pves=.;mcc_pabd=.;end;

        ** E section;
         if pfs_any_invl=1 then do;
              refill_pfs=.; cough_vd_pfs=.;end;

         if pfs_any_invl=1 and cough_vd_pfs~=1 then do;
              pves_pabd_cn=.;end;

         **PFS criteria:;
             **then calculate values in E16 and E17 based only on patients who
               met all three plausibility criteria;
              *HL - need to change plaus_pfs to press_pfs;
         if press_pfs~=1 then do;   *E16--E17;
              pfs_pves_bl=.;  pfs_pabd_bl=.;  pfs_pdet_bl=.;
              pves_qmax=.;  pabd_qmax=.;  pdet_qmax=.;end;

         if pt_void~=1 then do;*E18--E20;
               max_fl_pfs=.; flow_t_pfs=.; void_vol_pfs=.; end;

         if pfs_any_invl~=2 then do;
               void_mech=.; cghpstvd_pfs=.;
               pstcgh_pves=.; pstcgh_pabd=.; end;

*+++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++;
  *1. need to move some variables like vlpp_nored etc. to below from the front;
  *2. need to recalculated those variables because the recoding of the obove,
      values may not change.However, to make sure, I recommend this part:
      recalculate them as below:

    *D9;
     pdet_base_cmg=pves_base_cmg-pabd_base_cmg;

     *created mcc_pdet:D15a-D15b;
      mcc_pdet = mcc_pves - mcc_pabd;


    ******** calculate VLPP **********;
    * VLPP: mean of all three LPP's, if available
       if only 2 are available, take the mean of those two Otherwise, set to missing;
    * also calculate min and range;

   if (lpp_leak1^=. and lpp_leak2^=.) or (lpp_leak1^=. and lpp_leak3^=.)
       or (lpp_leak2^=. and lpp_leak3^=.) then do;
        vlpp_nored=mean(lpp_leak1,lpp_leak2,lpp_leak3);
        lppmin=min(lpp_leak1,lpp_leak2,lpp_leak3);
        lppmax=max(lpp_leak1,lpp_leak2,lpp_leak3);  end;

   *** Detrusor overactivity;
   if (detrusor_1^=. and detrusor_2^=.) or (detrusor_1^=. and detrusor_3^=.)
       or (detrusor_2^=. and detrusor_3^=.) then do;
         detrusor_mean=mean(detrusor_1,detrusor_2,detrusor_3);
         detrusormin=min(detrusor_1,detrusor_2,detrusor_3);
         detrusormax=max(detrusor_1,detrusor_2,detrusor_3);  end;

   *E16c recalculated, and will be used to analysis after discuss with Heather;
    pfs_pdet_bl=pfs_pves_bl -pfs_pabd_bl;

    **recreate pdet_qmax;
    pdet_qmax=pves_qmax-pabd_qmax;

    Label
        lppmin="min(lpp_leak1,lpp_leak2,lpp_leak3)"
        lppmax="max(lpp_leak1,lpp_leak2,lpp_leak3)"
        vlpp_nored="mean(lpp_leak1,lpp_leak2,lpp_leak3)"
```

```
657          detrusor_mean="mean(detrusor_1,detrusor_2,detrusor_3)"
658          detrusormin="min(detrusor_1,detrusor_2,detrusor_3)"
659          detrusormax="max(detrusor_1,detrusor_2,detrusor_3)";
660   *-------------------------------------------------------------------------------;
661      * create variables leak_grp, usi, and usinoinvalid;
662         *group pts according to when they first leaked;
663       leak_grp = .;
664            if leak_val < 0  then leak_grp = leak_val;
665       else if leak_val = 1  then leak_grp = 1;
666       else if leak_mcc = 1 then leak_grp = 3;
667       else leak_grp = 4;
668
669       *format leak_grp lk_grpf.;
670       label leak_grp="At what point did the patient leak? ";
671
672
673      *then create urinary stress incontinence (USI);
674       usi = .;
675            if leak_grp = 1 or leak_grp = 2 or leak_grp = 3 then usi = 1;
676       else if leak_grp = 4 then usi = 0;
677       else if leak_grp < 0 then usi = leak_grp;
678
679       label usi="urinary stress incontinence (USI)";
680
681       *USI variable that excludes those with missing leak_grp;
682        usinoinvalid = .;
683            if usi < 0 then usinoinvalid = .;
684       else if usi >= 0 then usinoinvalid = usi;
685       label usinoinvalid="USI variable that excludes those with missing leak_grp";
686
687   RUN;
NOTE: Missing values were generated as a result of performing an operation on missing values.
      Each place is given by: (Number of times) at (Line):(Column).
      14 at 284:32    14 at 331:25    103 at 383:29   103 at 392:24   19 at 512:44    14 at
623:33    44 at 626:27
      154 at 648:29   155 at 651:24
NOTE: There were 499 observations read from the data set WORK.F305A1.
NOTE: The data set WORK.F305A2 has 499 observations and 168 variables.
NOTE: DATA statement used (Total process time):
      real time           0.26 seconds
      cpu time            0.18 seconds


688
689   data fu_uds;
690      set f305a2;
691        if rand1=1 and inf305=1;
NOTE: There were 499 observations read from the data set WORK.F305A2.
NOTE: The data set WORK.FU_UDS has 499 observations and 168 variables.
NOTE: DATA statement used (Total process time):
      real time           0.21 seconds
      cpu time            0.17 seconds


692   proc sort; by master_id;
693   run;

NOTE: There were 499 observations read from the data set WORK.FU_UDS.
NOTE: The data set WORK.FU_UDS has 499 observations and 168 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


694
695   *** Baseline uds data ***;
696   data tomusm12_uds;
697    merge tmaid (keep=master_id aid) fu_uds;
698    by master_id;
699
700    drop master_id rando_dt NIF_MAX_FL NIF_MEAN_FL NIF_FLOW_T NIF_VOID_VOL NIF_PVR
```

```
701      NIF_PATTERN NIF_COMP_D NIF_EXAM_ID NIF_ABST_D NIF_ABST_ID NIF_EQUIP MUCP_VALID
702      MUCP_DESC MUCP_WI MUCP_LI MUCP_W2 MUCP_L2 MUCP_W3 MUCP_L3 LEGIBLE_SIG CATH_ATMOS
703      PVES_CMG_BL PABD_CMG_BL REAS_CMG_INV DESC_CMG_INV ANY_INVL_CMG PVES_BL_CMG PABD_BL_CMG
704      PDET_BL_CMG FIRST_DES STRONG_DES VAL_LEAK LPP_VOLUME LPP_LEAK_1 LPP_LEAK_2 LPP_LEAK_3
705      MCC_LEAK MCC PVES_MCC PABD_MCC DET_OVER DET_1 DET_LEAK_1 DET_2 DET_LEAK_2 DET_3
DET_LEAK_3
706      PFS_LEG_SIG PFS_CAT_ATM PFS_SIT_VD PFS_TRN_ADJ PFS_BL_INTP PVES_FUN_BL PABD_FUN_BL
PT_VOID
707      PVES_FUN_MAX PABD_FUN_MAX REAS_PFS_INV DESC_PFS_INV ANY_INVL_PFS PFS_REFILL PFS_PRECOUGH
708      PFS_CONCORD PVES_BL_PFS PABD_BL_PFS PDET_BL_PFS PVES_QMAX PABD_QMAX PFS_MAX_FL
PFS_FLOW_T
709      PFS_VOID_VOL PFS_VOID_PAT PFS_POSCOUGH PVES_FUN_C PABD_FUN_C CMG_COMP_D CMG_EXAM_ID
PFS_COMP_D
710      PFS_EXAM_ID UDS_RVW_D UDS_ABST_ID UDS_EQUIP FORMSTAT_ID DESTATUS rand1 inf305 dup
usinoinvalid;
711
712
713      label voil_vol_150 = "1: voided volume >= 150";
714
715      format voil_vol_150 valid_mucp mucp_2valid FUL_2valid cmg_any_invl leak_val detrusor
detrusor_leak_1
716           detrusor_leak_2 detrusor_leak_3 pfs_any_invl refill_pfs cough_vd_pfs pves_pabd_cn
cghpstvd_pfs
717           pstcgh_pves pstcgh_pabd ynb. pattern_nif flpatt. leak_mcc leakm. void_mech pfsvd.
valid_cmg plaus_cmg
718           pos_mcc plaus_mcc_pfs plaus_mcc valid_pfs plaus_base_pfs plaus_pfs_mcc
plaus_cough_pfs plaus_pfs press_pfs yna.
719           leak_grp lk_grpf. usi usilk.;
720
721  run;
NOTE: There were 597 observations read from the data set WORK.TMAID.
NOTE: There were 499 observations read from the data set WORK.FU_UDS.
NOTE: The data set WORK.TOMUSM12_UDS has 597 observations and 79 variables.
NOTE: DATA statement used (Total process time):
      real time           0.21 seconds
      cpu time            0.15 seconds


722
723
724  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
725
726  data matchfl.tomusm12_uds;
727     set tomusm12_uds;
728  run;

NOTE: There were 597 observations read from the data set WORK.TOMUSM12_UDS.
NOTE: The data set MATCHFL.TOMUSM12_UDS has 597 observations and 79 variables.
NOTE: DATA statement used (Total process time):
      real time           0.06 seconds
      cpu time            0.01 seconds
```