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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           2.40 seconds
      cpu time            1.20 seconds

1
2    ************************************************
3    ** tomusbase_uds: TOMUS baseline 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 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
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      '
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95                2='Current     ';
NOTE: Format SMKST has been output.
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
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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.
NOTE: The data set WORK.RANDA has 597 observations and 18 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


141  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           0.04 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 baseline---------------------------;
145  data f305a0;
146     merge randa (in=rand keep=master_id rando_dt)
147           f305 (in=a where=(visit='TBAS'));
148     by master_id;
149     if rand then rand1=1;
150     if a then inf305=1;
151
152     label rand1='1:randomized';
NOTE: There were 597 observations read from the data set WORK.RANDA.
NOTE: There were 608 observations read from the data set WORK.F305.
      WHERE visit='TBAS';
NOTE: The data set WORK.F305A0 has 610 observations and 89 variables.
NOTE: DATA statement used (Total process time):
      real time           0.17 seconds
      cpu time            0.07 seconds


153  proc sort;  by master_id visit;run;

NOTE: There were 610 observations read from the data set WORK.F305A0.
NOTE: The data set WORK.F305A0 has 610 observations and 89 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


154
155  data f305a1;
156     set f305a0;
157
158  *** recode pdet_bl_cmg so that unless pves_bl_cmg and pabd_bl_cmg are missing,
159      then pdet_blcmg_sk is a valid negative number, not a special value***;
160      if pves_bl_cmg >0 and  pabd_bl_cmg >0 then do;
161        pdet_bl_cmg_ck=pves_bl_cmg-pabd_bl_cmg; end;
162   label pdet_bl_cmg_ck = "F305:computed to check D9.pdet_bl_cmg_ck=pves_bl_cmg-pabd_bl_cmg";
163
164  *** recode pabd_bl_pfs so that unless pves_bl_pfs is skipped and pabd_bl_pfs = -2,
165      then pabd_pfsbl_sk is a valid negative number, not a special value;
```

```
166
167      if pves_bl_pfs>0 and  pabd_bl_pfs>0 then do;
168        pdet_bl_pfs_ck= pves_bl_pfs - pabd_bl_pfs;end;
169    label pdet_bl_pfs_ck = "F305:computed to check E16c:pdet_bl_pfs_ck= pves_bl_pfs - and pabd_bl_pfs";
170
171  ***Check duplicate based on ID and visit;
172   by master_id visit;
173    dup=( (first.visit ^= last.visit) or
174          (first.visit=0 and last.visit=0) );
175  run;

NOTE: There were 610 observations read from the data set WORK.F305A0.
NOTE: The data set WORK.F305A1 has 610 observations and 92 variables.
NOTE: DATA statement used (Total process time):
      real time           0.17 seconds
      cpu time            0.10 seconds


176
177
178  ********************************************************************************;
179  data f305a2;
180     set f305a1;
181
182   ** Recode B section;
183     if nif_void_vol>=150 then voil_vol_150=1; else voil_vol_150=2;
184
185      if nif_max_fl <0  then max_fl_nif = .;  else max_fl_nif = nif_max_fl;
186      if nif_mean_fl <0 then mean_fl_nif = .; else mean_fl_nif = nif_mean_fl;
187      if nif_pattern <0 then pattern_nif = .; else pattern_nif = nif_pattern;
188      if nif_flow_t <0  then flow_t_nif = .;  else flow_t_nif = nif_flow_t;
189      if nif_void_vol<0 then void_vol_nif =.; else void_vol_nif = nif_void_vol;
190      if nif_pvr  <0    then pvr_nif = .;     else pvr_nif = nif_pvr;
191
192      label
193          void_vol_nif="F305:B0.Is voided volume (B4) at least 150 ml?"
194          max_fl_nif = "F305:B1.NIF max flow"
195          mean_fl_nif = "F305:B2.NIF mean flow"
196          pattern_nif = "F305:B6.NIF flow pattern"
197          flow_t_nif = "F305:B3.NIF time to max flow"
198          void_vol_nif = "F305:B4.NIF voided volume"
199          pvr_nif = "F305:B5. NIF post-void residual";
200
201   *-------------------------------------------------------------------------------;
202   ** Recode C section;
203    if mucp_valid>0 then valid_mucp=mucp_valid;
204
205    ** according C1a(description), UDS group decided to make following change;
206    **we dont know whether or not to change in ADEPT;
207    if master_id in ("191000065" "131000525" "131000376" "131000354" "131000194" "131000172"
208                     "131000592" "112000365" "111000307" "111000227")
209                 then valid_mucp=1;
210
211    *****create new variables and set some C2--C7 to missing based on UDS group discusion***;
212    *****we dont know whether or not to change in ADEPT;
213    if mucp_li>50 then do; mucp_li=.;mucp_wi=.;end;
214    if mucp_l2>50 then do; mucp_l2=.;mucp_w2=.;end;
215    if mucp_l3>50 then do; mucp_l3=.;mucp_w3=.;end;
216
217    if mucp_wi>0 then mucpwi=mucp_wi;
218    if mucp_w2>0 then mucpw2=mucp_w2;
219    if mucp_w3>0 then mucpw3=mucp_w3;
220
221    if mucp_li>0 then mucpli=mucp_li;
222    if mucp_l2>0 then mucpl2=mucp_l2;
223    if mucp_l3>0 then mucpl3=mucp_l3;
224
225    if master_id in ("131000354" "142000039" "151000174") then do;
226       mucpwi=.;mucpw2=.; mucpw3=.;mucpli=.;mucpl2=.;mucpl3=.;end;
```

```
227
228    if master_id in ("131000592" "191000407" "181000097" "181000257" "191000452")
229       then do; mucpwi=.;mucpli=.;end;
230
231    if master_id in ("131000423" "171000052" )then do; mucpw2=.;mucpl2=.;end;
232
233    if master_id in ("112000014" "191000441" "191000623") then do; mucpw3=.;mucpl3=.;end;
234
235    **compute mean of mucp_w and mucp_l given there are at least two valid value of three***;
236      * MUCP: mean of all three MUCP, if available
237          if only 2 are available, take the mean of those two
238          otherwise, set to missing;
239
240    if (mucpwi^=. and mucpw2^=.) or (mucpwi^=. and mucpw3^=.) or (mucpw2^=. and mucpw3^=.)
241       then do; mucP_w=mean(mucpwi,mucpw2,mucpw3);end;
242
243    if (mucpli^=. and mucpl2^=.) or (mucpli^=. and mucpl3^=.) or (mucpl2^=. and mucpl3^=.)
244       then do;   mucP_l=mean(mucpli,mucpl2,mucpl3); end;
245
246    ** indicator for MUCP which has at least two valid values;
247    if (mucpwi^=. and mucpw2^=.) or (mucpwi^=. and mucpw3^=.) or (mucpw2^=. and mucpw3^=.)
248       then mucp_2valid=1;
249       else if mucpwi=. and mucpw2=. and mucpw3=. then mucp_2valid=2;
250       else mucp_2valid=2;
251
252    ** indicator for FUL which has at least two valid values;
253    if (mucpli^=. and mucpl2^=.) or (mucpli^=. and mucpl3^=.) or (mucpl2^=. and mucpl3^=.)
254       then FUL_2valid=1;
255       else if mucpli=. and mucpl2=. and mucpl3=. then FUL_2valid=2;
256       else FUL_2valid=2;
257
258    label
259        valid_mucp="F35Q:C1.are all mucp data valid"
260        mucpwi = "F305:C2 if mucp_wi>0"
261        mucpw2 = "F305:C4 if mucp_w2>0"
262        mucpw3 = "F305:C6 if mucp_w3>0"
263        mucp_2valid="=1:at least two valid values of MUCP"
264
265        mucpli = "F305:C3 if mucp_Li>0"
266        mucpl2 = "F305:C5 if mucp_L2>0"
267        mucpl3 = "F305:C7 if mucp_L3>0"
268        mucP_w= "mean(mucpwi,mucpw2,mucpw3)"
269        mucP_L= "mean(mucpLI,mucpL2,mucpL3)"
270        FUL_2valid="=1:at least two valid values of FUL";
271   *-------------------------------------------------------------------------------------;
272   ** Recode D section:CMG;
273
274      if any_invl_cmg>0 then cmg_any_invl = any_invl_cmg;
275      if pves_bl_cmg <0 then pves_base_cmg = .; else pves_base_cmg = pves_bl_cmg;
276      if pabd_bl_cmg <0 then pabd_base_cmg = .; else pabd_base_cmg = pabd_bl_cmg;
277
278      *D9 recalculated, and will be used to analysis after discuss with Heather,same as SISTEr;
279      pdet_base_cmg=pves_base_cmg-pabd_base_cmg;
280      /*if pdet_base_cmg<-5 then pdet_base_cmg=.;*/
281
282      if val_leak>0 then leak_val=val_leak;
283      if lpp_volume>0 then volume_lpp= lpp_volume;
284
285      if first_des >0 then first_desire = first_des;
286      if strong_des >0 then strong_desire = strong_des;
287      if lpp_leak_1>0 then  lpp_leak1=lpp_leak_1;
288      if lpp_leak_2>0 then  lpp_leak2=lpp_leak_2;
289      if lpp_leak_3>0 then  lpp_leak3=lpp_leak_3;
290
291      if mcc_leak>0 then leak_mcc = mcc_leak;
292
293      if mcc <0 then vol_mcc = .; else vol_mcc = mcc;
294      if pves_mcc >0  then mcc_pves = pves_mcc;
295      if pabd_mcc >0  then mcc_pabd = pabd_mcc;
```

```
296
297      if det_over>0 then detrusor = det_over;
298
299      if det_1 >0   then detrusor_1 = det_1;
300      if det_leak_1>0 then detrusor_leak_1 = det_leak_1;
301
302      if det_2>0   then detrusor_2 = det_2;
303      if det_leak_2>0 then detrusor_leak_2 = det_leak_2;
304
305      if det_3 >0   then detrusor_3 = det_3;
306      if det_leak_3>0 then detrusor_leak_3 = det_leak_3;
307
308
309    *****inconsistency of D1--D5 and D6 on randomized IDs(no in baseline)*****;
310    *****According UDS group and heather,the following IDs (some other waiting for query back)
311         with D6=1 will be set D7--D9,D13a--D13c and D15a D15b to missing,
312         we dont know whether or not to change in ADEPT;
313    *****depend on queries;
314   if master_id in ("151000447" "161000142" "161000357" "161000460")
315         /* or cmg_any_invl=1 */then do;
316         pves_base_cmg=.;
317         pabd_base_cmg=.;
318         pdet_base_cmg=.;
319         lpp_leak1=.;
320         lpp_leak2=.;
321         lpp_leak3=.;
322         mcc_pves=.;
323         mcc_pabd=.;end;
324
325     *created mcc_pdet:D15a-D15b;
326      mcc_pdet = mcc_pves - mcc_pabd;
327
328  **updated by liyuan 1/22/09;
329   if leak_val=2 then do;
330         volume_lpp=.;
331         lpp_leak1=.;
332         lpp_leak2=.;
333         lpp_leak3=.;
334    end;
335
336
337     label
338          cmg_any_invl = "F305:D6.FMCP Any invalid conditions for CMG?"
339          pves_base_cmg = "F305:D7.Pves at CMG baseline"
340          pabd_base_cmg = "F305:D8.Pabd at CMG baseline"
341          pdet_base_cmg = "F305:D9.Pdet at CMG baseline"
342          first_desire = "F305:D10.Volume at first desire"
343          strong_desire = "F305:D11.Volume at strong desire"
344          leak_val="F305:D12. Did leakage occur with valsalva"
345          volume_lpp="F305:D13. At what volume"
346          lpp_leak1= "F305:D13a. raw pves at 1st leakage"
347          lpp_leak2= "F305:D13b. raw pves at 2nd leakage"
348          lpp_leak3= "F305:D13c. raw pves at 3rd leakage"
349          leak_mcc ="F305:D14.if mcc_leak>0 then leak_mcc = mcc_leak"
350          vol_mcc  ="F305:D15. Bladder volume at MCC"
351          mcc_pves="F305:D15a. pves at MCC"
352          mcc_pabd="F305:D15b. pabd at MCC"
353          detrusor = "F305:D16.Detrusor overactivity?"
354          detrusor_1 = "F305:D16a.Vol at DO occurence 1"
355          detrusor_leak_1 = "F305:D16a1.Leaking at DO occurence 1?"
356          detrusor_2 = "F305:D16b.Vol at DO occurence 2"
357          detrusor_leak_2 = "F305:D16b1.Leaking at DO occurence 2?"
358          detrusor_3 = "F305:D16c.Vol at DO occurence 3"
359          detrusor_leak_3 = "F305:D16c1.Leaking at DO occurence 3?"
360          mcc_pdet="F305:D15a-D15b:mcc_pves - mcc_pabd";
361
362   *-------------------------------------------------------------------------------------;
363
364   ** Recode E section:PFS;
```

```
** there is no inconsistency of E1--E11 and E12 on randomized IDs for baseline;
** and these variables have not been used, so have not recoded;


  if any_invl_pfs>0 then pfs_any_invl = any_invl_pfs;
  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 baseline"
       pfs_pabd_bl = "F305:E16b.Pabd at PFS baseline"
       pfs_pdet_bl = "F305:E16c.Pdet at PFS baseline"
   /*  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 baseline
        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 baseline not between -5 and 10, then drop all CMG pressure values
```

```
434          other than baseline ;
435
436         if valid_cmg=0 then plaus_cmg=0;else plaus_cmg=(-5 le pdet_base_cmg le 10);
437          * = 1 if CMG is plausible;
438          *HL - note: plaus_cmg should be used as the first criteria for deciding if PFS
439                     pressure values were valid;
440
441         label plaus_cmg="CMG plausibility first criteria";
442
443      *<<<<2nd(a) plausibility>>>>;
444
445         *CMG plausibility second criteria (part a):pos_mcc;
446         *if pdet at mcc < -5 then drop all MCC pressure values;
447         *look at plausibility of MCC pressures in 2 steps: neg and rel to PFS BL;
448
449         if plaus_cmg=0 then pos_mcc=0;else pos_mcc=(mcc_pdet ge -5);
450           * = 1,if pdet at MCC is plausible;
451         label pos_mcc="CMG plausibility second criteria (part a)";
452
453       *<<<<2nd(b) plausibility>>>>;
454
455         *CMG plausibility second criteria (part b):plaus_mcc_pfs;
456         *pdet at PFS baseline - pdet at MCC < -15 => drop all MCC pressure values;
457
458         if plaus_cmg=0 then plaus_mcc_pfs=0;    else if pfs_pdet_bl<-5 then plaus_mcc_pfs=1;
459          *MODIFICATION 3/20/2006:if pdet at PFS BL out of range, don't compare;
460         else plaus_mcc_pfs = (mcc_pdet - pfs_pdet_bl le 15);
461         Label plaus_mcc_pfs="CMG plausibility second criteria (part b)";
462
463         *for overall plausibility - for now keep it as not considering number 2 part b;
464         * MODIFICATION 7/25/2006: change MCC plausibility criteria: no comparision to
465         PFS baseline;
466
467         plaus_mcc = pos_mcc;
468         *plaus_mcc = pos_mcc * plaus_mcc_pfs;*MCC pressures plausible if both criteria met;
469
470         label plaus_mcc="does patient meet all  plausibility criteria of CMG?";
471         *CMG pressure values: Essentially, D7, D8 and D9 should be based on those with valid_cmg =
yes
472         and don’t have to be based on plaus_mcc = yes., D13a, D13b, D13c, D15a, D15b were considered
473         plausible if there were no invalid conditions for CMG in the validity section above
474         and there were no implausible conditions as per plausibility criteria 1 and 2a above.
475
476
477   *-------------------------------------------------------------------------------------;
478   **PFS: define validity and plausibility criteria
479       <<<<1>>>>;
480         **PFS:creates second validity criterion:valid_pfs;
481         **if the reviewer determined there were invalid conditions for the PFS or
482           Pves or Pabd at baseline was less than 0 then PFS is invalid;
483         **based on E12,and E16a,E16b;
484         if pfs_any_invl = 1 or pfs_pves_bl < 0 or pfs_pabd_bl < 0 then valid_pfs = 0;
485           else valid_pfs = 1;
486         label valid_pfs="PFS:second validity criterion: if NOT E12=1 or E16a<0 or E16b<0";
487
488       *<<<<2>>>>;
489         **PFS plausibility first criteria: plaus_base_pfs;
490         **(pdet at PFS baseline - pdet at MCC)>15 => drop all PFS pressure values
491           pdet at PFS baseline < -5 => drop all PFS pressure values;
492         **based on E16a--E16c;
493
494         if valid_pfs = 0 then plaus_base_pfs = 0;
495           else plaus_base_pfs = (pfs_pdet_bl ge -5);    * = 1 if PFS is plausible;
496         label plaus_base_pfs="PFS 1st plausibility criterion";
497
498       *<<<<3>>>>;
499         **PFS plausibility second criteria: plaus_pfs_mcc;
500         **based on D15a,D15b,and E16a--E16c;
501
```

```
          if valid_pfs = 0 then plaus_pfs_mcc = 0; else if mcc_pdet lt -5
             then plaus_pfs_mcc= 0;*if pdet at MCC out of range, don't compare;
             else plaus_pfs_mcc=(pfs_pdet_bl-mcc_pdet le 15);* = 1 if PFS is plausible;

          label plaus_pfs_mcc="PFS:second plausibility criterion";

     *<<<<4>>>>;
         **PFS:third plausibility criterion:plaus_cough_pfs;
         **if reviewer indicated there was not 70% concordance,
           pfs is implausible and exclude all PFS pressure values;
         if valid_pfs = 0 or pves_pabd_cn = 2 then plaus_cough_pfs = 0;
             else plaus_cough_pfs = 1;

         label plaus_cough_pfs="PFS:third plausibility criterion";

     *<<<<5>>>>;
         ** does patient meet all 3 plausibility criteria?;
          plaus_pfs = plaus_base_pfs * plaus_pfs_mcc * plaus_cough_pfs;

         label plaus_pfs="does patient meet all 3 plausibility criteria of PFS?";


     *HL - need to add in this variable to account for the CMG invalid values;
         if plaus_cmg = 0 or valid_pfs = 0 or plaus_pfs = 0 then press_pfs = 0;
             else press_pfs = 1;                                          *analyzable;

         label press_pfs="criteria for PFS(E16 and E17)";

     **then calculate values in E16 and E17 based only on patients who
       met press_pfs=1;

*-------------------------------------------------------------------------------------;
       ********set the variables that do not meet criteria to missing********;
         **B section;
         if voil_vol_150=2 then do;
               max_fl_nif=.;
               mean_fl_nif=.;
               flow_t_nif=.;
               void_vol_nif=.;
               pvr_nif=.;
               pattern_nif=.;end;

         **C section;
          If mucp_2valid=2 or FUL_2valid=2 then do;
               mucP_w=.;
               mucP_l=.;end;

         **D section;
               *HL - change cmg_any_invl=1 to also include valid_cmg ~= 1;
          If cmg_any_invl=1 or valid_cmg~=1 then do;
               pves_base_cmg=.;
               pabd_base_cmg=.;
               pdet_base_cmg=.;end;
          if leak_val~=1 then do;
               volume_lpp=.;end;
          if cmg_any_invl=1 or leak_val~=1 then do;
               lpp_leak1=.; lpp_leak2=.; lpp_leak3=.;
               vlpp_nored=.; lppmin=.; lppmax=.; end;

          If cmg_any_invl=1 then do;
               mcc_pves=.; mcc_pabd=.;mcc_pdet=.; end;

          if detrusor~=1 then do;
               detrusor_1=.;  detrusor_leak_1=.;
               detrusor_2=.;  detrusor_leak_2=.;
               detrusor_3=.;  detrusor_leak_3=.;
               detrusor_mean=.;  detrusormin=.;  detrusormax=.; end;

           *CMG Criteria:;
```

```
               *HL - take out D7, D8, D9;
               *CMG pressure values in  D13a, D13b, D13c, D15a, D15b were
                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;
```

```
640
641      Label
642          lppmin="min(lpp_leak1,lpp_leak2,lpp_leak3)"
643          lppmax="max(lpp_leak1,lpp_leak2,lpp_leak3)"
644          vlpp_nored="mean(lpp_leak1,lpp_leak2,lpp_leak3)"
645          detrusor_mean="mean(detrusor_1,detrusor_2,detrusor_3)"
646          detrusormin="min(detrusor_1,detrusor_2,detrusor_3)"
647          detrusormax="max(detrusor_1,detrusor_2,detrusor_3)";
648   *-------------------------------------------------------------------------------;
649      * create variables leak_grp, usi, and usinoinvalid;
650         *group pts according to when they first leaked;
651      leak_grp = .;
652           if leak_val < 0  then leak_grp = leak_val;
653      else if leak_val = 1  then leak_grp = 1;
654      else if leak_mcc = 1 then leak_grp = 3;
655      else leak_grp = 4;
656
657      label leak_grp="At what point did the patient leak? ";
658
659     *then create urinary stress incontinence (USI);
660      usi = .;
661           if leak_grp = 1 or leak_grp = 2 or leak_grp = 3 then usi = 1;
662      else if leak_grp = 4 then usi = 0;
663      else if leak_grp =-1 then usi = leak_grp;
664
665      label usi="urinary stress incontinence (USI)";
666
667      *USI variable that excludes those with missing leak_grp;
668       usinoinvalid = .;
669           if usi < 0 then usinoinvalid = .;
670      else if usi >= 0 then usinoinvalid = usi;
671      label usinoinvalid="USI variable that excludes those with missing leak_grp";
672
673   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).
      48 at 279:32    45 at 326:25    151 at 378:29   152 at 387:24   1 at 460:40     17 at 504:44    48
at 611:33
      69 at 614:27    200 at 636:29   200 at 639:24
NOTE: There were 610 observations read from the data set WORK.F305A1.
NOTE: The data set WORK.F305A2 has 610 observations and 168 variables.
NOTE: DATA statement used (Total process time):
      real time           0.25 seconds
      cpu time            0.15 seconds


674
675   data baseline_uds;
676      set f305a2;
677        if rand1=1 and inf305=1;

NOTE: There were 610 observations read from the data set WORK.F305A2.
NOTE: The data set WORK.BASELINE_UDS has 595 observations and 168 variables.
NOTE: DATA statement used (Total process time):
      real time           0.15 seconds
      cpu time            0.07 seconds


678   proc sort; by master_id;
679   run;

NOTE: There were 595 observations read from the data set WORK.BASELINE_UDS.
NOTE: The data set WORK.BASELINE_UDS has 595 observations and 168 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.03 seconds
      cpu time            0.03 seconds

680
```

```
681  *** Baseline uds data ***;
682  data tomusbase_uds;
683   merge tmaid (keep=master_id aid) baseline_uds;
684   by master_id;
685
686   drop MASTER_ID rando_dt NIF_MAX_FL NIF_MEAN_FL NIF_FLOW_T NIF_VOID_VOL NIF_PVR
687      NIF_PATTERN NIF_COMP_D NIF_EXAM_ID NIF_ABST_D NIF_ABST_ID NIF_EQUIP MUCP_VALID
688      MUCP_DESC MUCP_WI MUCP_LI MUCP_W2 MUCP_L2 MUCP_W3 MUCP_L3 LEGIBLE_SIG CATH_ATMOS
689      PVES_CMG_BL PABD_CMG_BL REAS_CMG_INV DESC_CMG_INV ANY_INVL_CMG PVES_BL_CMG PABD_BL_CMG
690      PDET_BL_CMG FIRST_DES STRONG_DES VAL_LEAK LPP_VOLUME LPP_LEAK_1 LPP_LEAK_2 LPP_LEAK_3
691      MCC_LEAK MCC PVES_MCC PABD_MCC DET_OVER DET_1 DET_LEAK_1 DET_2 DET_LEAK_2 DET_3 DET_LEAK_3
692      PFS_LEG_SIG PFS_CAT_ATM PFS_SIT_VD PFS_TRN_ADJ PFS_BL_INTP PVES_FUN_BL PABD_FUN_BL PT_VOID
693      PVES_FUN_MAX PABD_FUN_MAX REAS_PFS_INV DESC_PFS_INV ANY_INVL_PFS PFS_REFILL PFS_PRECOUGH
694      PFS_CONCORD PVES_BL_PFS PABD_BL_PFS PDET_BL_PFS PVES_QMAX PABD_QMAX PFS_MAX_FL PFS_FLOW_T
695      PFS_VOID_VOL PFS_VOID_PAT PFS_POSCOUGH PVES_FUN_C PABD_FUN_C CMG_COMP_D CMG_EXAM_ID PFS_COMP_D
696      PFS_EXAM_ID UDS_RVW_D UDS_ABST_ID UDS_EQUIP FORMSTAT_ID DESTATUS rand1 inf305 dup usinoinvalid
VISIT;
697
698
699      label voil_vol_150 = "1: voided volume >= 150";
700
701      format voil_vol_150 valid_mucp mucp_2valid FUL_2valid cmg_any_invl leak_val detrusor
detrusor_leak_1
702          detrusor_leak_2 detrusor_leak_3 pfs_any_invl refill_pfs cough_vd_pfs pves_pabd_cn
cghpstvd_pfs
703          pstcgh_pves pstcgh_pabd ynb. pattern_nif flpatt. leak_mcc leakm. void_mech pfsvd. valid_cmg
plaus_cmg
704          pos_mcc plaus_mcc_pfs plaus_mcc valid_pfs plaus_base_pfs plaus_pfs_mcc plaus_cough_pfs
plaus_pfs press_pfs yna.
705          leak_grp lk_grpf. usi usilk.;
706
707  run;
NOTE: There were 597 observations read from the data set WORK.TMAID.
NOTE: There were 595 observations read from the data set WORK.BASELINE_UDS.
NOTE: The data set WORK.TOMUSBASE_UDS has 597 observations and 78 variables.
NOTE: DATA statement used (Total process time):
      real time           0.17 seconds
      cpu time            0.10 seconds
```