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Integrity Check for the Interstitial Cystitis Clinical Trials Group (ICCTG) Bacillus Calmette Guerin (BCG) study

As a partial check of the integrity of the ICCTG-BCG dataset archived in the NIDDK data repository, a set of tabulations was performed to verify that published results can be reproduced using the archived dataset. Analyses were performed to duplicate selected results for the data published by Mayer et al [1] in the *Journal of Urology* in April 2005. The results of this dataset integrity check (DSIC) are described below. The full text of the *Journal of Urology* article can be found in Attachment 1, and the SAS code for our tabulations is included in Attachment 2.

The intent of this DSIC is to provide confidence that the data distributed by the NIDDK repository is a true copy of the study data. Our intent is ***not*** to assess the integrity of the statistical analyses reported by study investigators. As with all statistical analyses of complex datasets, complete replication of a set of statistical results should not be expected on a first (or second) exercise in secondary analysis. This occurs for a number of reasons including differences in the handling of missing data, restrictions on cases included in samples for a particular analysis, software coding used to define complex variables, etc. Experience suggests that most discrepancies can ordinarily be resolved by consultation with the study data coordinating center (DCC), however this process is labor-intensive for both DCC and Repository staff. It is thus not our policy to resolve every discrepancy that is observed in an integrity check. Specifically, we do not attempt to resolve minor or inconsequential discrepancies with published results or discrepancies that involve complex analyses, *unless NIDDK Repository staff suspect that the observed discrepancy suggests that the dataset may have been corrupted in storage, transmission, or processing by repository staff*. We do, however, document in footnotes to the integrity check those instances in which our secondary analyses produced results that were not fully consistent with those reported in the target publication.

Background. The Interstitial Cystitis Clinical Trials Group (ICCTG) trial was a randomized clinical trial using a two armed design that compared the efficacy of Bacillus Calmette-Guerin (BCG) therapy to a placebo. BCG was instilled into the bladder via catheter.

The study was conducted in two phases. The first phase consisted of the initial treatment and follow-up for primary and secondary endpoints. The primary endpoints were evaluated in the post-treatment follow-up phase 34 weeks after randomization, when patients were identified as responders or non-responders based on their responses to the global assessment questionnaire and their use of medications for IC symptoms. In the second phase of the study, nonresponders were offered open label BCG treatment. The paper by Mayer et al. provides the main study results for the first phase.

In this DSIC, we compared our results to the published results in Table 1 (Baseline patient characteristics by treatment arm) and the descriptive results in Table 2 (Efficacy outcomes by treatment arm) of Mayer et al. P-values in Table 2, based on the exact conditional test version of the Mantel-Haenszel test and longitudinal data analysis with random effects regression models, were not checked.

The tables in this DSIC reproduce exactly the row descriptors and footnotes from Tables 1 and 2.

Baseline Characteristics by Treatment Arm. Table A lists the datasets, data forms, data variables, and algorithms for derived analysis variables that we used in our replication for Table 1 of Mayer et al. The dataset “primaryanaldata” is an analysis file provided by the DCC along with the form-based files. For this dataset the forms upon which the analysis variables are based are shown in parentheses, because we did not use the original form-based variables – rather, we used the variables as contained in primaryanaldata. Based on the maximum possible value of 42 for the Wisconsin IC Symptom Inventory

as shown in the descriptor of Table 1, we determined that only 7 of the 25 items on the Wisconsin Symptom Inventory were included, so we identified those that were related to interstitial cystitis, as shown in Table A.

The published results and the DSIC results are shown side by side in Table B. Again, row descriptors and footnotes are reproduced from Table 1. All DSIC results agreed with the published results, within the limits of rounding.

Efficacy outcomes by treatment arm. Table C lists the datasets, data forms, data variables, and algorithms for derived analysis variables that we used in our replication of Table 2 of Mayer et al., and Table D contains the published results and the DSIC results. Values shown in **bold** do not agree (within rounding) with the published values.

Primary outcome. The first few rows in Table D show the results for the analysis of the primary outcome of the trial, the adjudicated responders at week 34. The DSIC results agree with the published results.

Secondary outcomes. The remainder of Table D considers the changes in secondary outcomes from baseline to week 34. Note that “functional capacity” in this table is synonymous with the label "max 24-hr voided vol" in Table 1 of Mayer et al. (Table B). However, as confirmed by the data center, for functional capacity the maximum of nonmissing voids was used for each subject, whereas for max 24-hr voided volume subjects with any missing void volumes were excluded (compare definitions in Tables C and A).

The first sentence of the footnote (*) states - "Mean values for the analysis of secondary outcomes were based on only those subjects who had complete data for all points, excluding withdrawals and those with missing data." This seemed to be open to alternative interpretations, since the data come from several different forms:

- 24-hr frequency and functional capacity are derived from the VOID (Voiding Diary).
- Pain score and urgency score come from the FUSYM (Follow-Up Symptoms) form (and from the primaryanaldata file for the baseline).
- O'Leary-Sant IC Symptom Index and Problem Index come from the SYM form.
- Wisconsin IC Symptom Inventory is derived from the WIS form.

Furthermore, these forms are not all collected at the same time points. All measures are collected at Visit 2 (baseline), 8, 11, 13, and 15 (week 34), except for those derived from the voiding diary, which is not collected at Visit 8.

So, initially, we looked first (to get the lay of the land, and because it was easier to program) at available nonmissing data for the change from baseline to week 34 for each outcome separately. These results for this “available data” analysis are shown in the columns labeled “DSIC #1”. Surprisingly, almost all of the descriptive statistics matched within rounding. For functional capacity, however, the means and SDs did not match, and the n’s did not agree with the footnote (†). Also, for the O’Leary-Sant indices and the Wisconsin IC symptom inventory the n’s in the placebo group were larger than the “No. subjects with complete data”.

We then attempted to find the subset of subjects with "complete" data, on a per form basis. [The ICCTG DCC has confirmed that the analyses were based on complete data on a per form basis.] For each form we restricted the subjects to those with a form at each visit. The results are shown in the columns labeled “DSIC #2” in Table D. This time all of the n's were less than or equal to the 126 Placebo and 120 BCG patients indicated in the “No. subjects with complete data” row, as expected. Also, the n’s of 113 and 109

for the 24-hour frequency and functional capacity now matched those in the footnote (†), and the means and SDs for the latter now agreed with the published data. However, the means and SDs for 24-hour frequency did not. In addition some of the means and standard deviations for the remaining variables did not match. Finally, the ICCTG DCC has indicated that the complete data analysis of the pain and urgency scores from the FUSYM form had n's equal to 126 for Placebo and 120 for BCG, but we get those numbers only when we use all available data (DSIC #1).

Summary. In this DSIC, descriptive results for the baseline measurements and the primary outcome agreed with published values. For secondary outcomes, agreement was found only by using different missing data algorithms for different variables (two within the same form), and the denominators remain uncertain.

Table A. Datesets, forms, variables, and analysis variable algorithms for Mayer et al (2005) Table 1.

	Primary Dataset(s)	Data form(s)	Data variable(s)	Algorithm
No. subjects	primaryanaldata			
No. female (%)	primaryanaldata	(DEMO)	DEM2	DEM2
No. race (%):	primaryanaldata	(DEMO)	DEM3	race2: if dem3 in (1 4 6 98) then race2 = 98 ; else race2 = dem3 ;
White				
Black				
Hispanic				
Other				
No. with symptoms more than 52 wks (%)	primaryanaldata	(BSYM1)	BSYM1_BSY4	BSYM1_BSY4
Mean age at study entry ± SD	primaryanaldata	(DEMO)	VDATE, DEM1	age = (vdate - dem1)/365.25/24/60/60
Mean 24-hr frequency ± SD	voidlog_orig_p1	VOID		n_seq = number of voids recorded
Mean av 24-hr voided vol (cc) ± SD*	voidlog_orig_p1	VOID	VOIDLG02	mean_voidvol = mean of void volumes for the subject over 24 hours; excludes any subject with one or more missing void volumes
Mean max 24-hr voided vol (cc) ± SD	voidlog_orig_p1	VOID	VOIDLG02	max_voidvol = maximum of void volumes for the subject over 24 hours; excludes any subject with one or more missing void volumes
Mean pain score ± SD (0–9)†	primaryanaldata	(BSYM1)	BSYM1_BSY1, BSYM1_BSY2	painsc = (bsym1_bsy1 + bsym2_bsy1)/2 ;
Mean urgency score ± SD (0–9)†	primaryanaldata	(BSYM2)	BSYM2_BSY1, BSYM2_BSY2	urgsc = (bsym1_bsy1 + bsym2_bsy1)/2 ;
Mean O'Leary-Sant IC Symptom Index (0–20) ± SD	sym_derived_p1	SYM	SYMSCR	SYMSCR
Mean O'Leary-Sant IC Problem Index (0–16) ± SD	sym_derived_p1	SYM	PROBSCR	PROBSCR
Mean Wisconsin IC Symptom Inventory (0–42) ± SD	wis_derived_p1	WIS	WIS1, WIS2, WIS10, WIS18, WIS21, WIS23, WIS25	wisbladder: if nmiss(wis1, wis2, wis10, wis18, wis21, wis23, wis25)=0 then wisbladder = sum(wis1, wis2, wis10, wis18, wis21, wis23, wis25) ; excludes any subject with one or more missing items.

* Voided volumes were missing for 2 subjects on placebo and 1 subject on BCG.

† Average of 2 baseline scores.

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Table B. DSIC results for Table 1 of Mayer et al (2005), "Baseline patient characteristics by treatment arm".

All results agree within rounding.

	Placebo			BCG		
	Published	DSIC		Published	DSIC	
	Mean ± SD or n (%)	Mean or n	SD or %	Mean ± SD or n (%)	Mean or n	SD or %
No. subjects	134	134		131	131	
No. female (%)	111 (83)	111	82.84	106 (81)	106	80.92
No. race (%):						
White	116 (87)	116	86.57	114 (87)	114	87.02
Black	11 (8)	11	8.21	6 (5)	6	4.58
Hispanic	3 (2)	3	2.24	2 (2)	2	1.53
Other	4 (3)	4	2.99	9 (7)	9	6.87
No. with symptoms more than 52 wks (%)	128 (96)	128	95.52	126 (96)	126	96.18
Mean age at study entry ± SD	47.3 ± 13.2	47.22	13.21	48.1 ± 13.9	48.09	13.86
Mean 24-hr frequency ± SD	18.0 ± 7.6	17.99	7.61	19.9 ± 9.8	19.86	9.83
Mean av 24-hr voided vol (cc) ± SD*	114 ± 60	113.86	60.35	117 ± 66	116.57	65.54
Mean max 24-hr voided vol (cc) ± SD	255 ± 144	254.58	144.16	272 ± 161	271.52	161.04
Mean pain score ± SD (0–9)†	6.7 ± 1.3	6.68	1.27	6.9 ± 1.2	6.87	1.22
Mean urgency score ± SD (0–9)†	7.0 ± 1.2	7.02	1.17	7.0 ± 1.4	6.99	1.41
Mean O'Leary-Sant IC Symptom Index (0–20) ± SD	14.5 ± 3.2	14.48	3.24	14.4 ± 3.2	14.41	3.24
Mean O'Leary-Sant IC Problem Index (0–16) ± SD	12.8 ± 2.5	12.84	2.46	12.6 ± 2.4	12.649	2.37
Mean Wisconsin IC Symptom Inventory (0–42) ± SD	32.1 ± 7.2	32.10	7.19	31.5 ± 7.6	31.51	7.56

* Voided volumes were missing for 2 subjects on placebo and 1 subject on BCG.

† Average of 2 baseline scores.

Table C. Datesets, forms, variables, and analysis variable algorithms for Mayer et al (2005) Table 2.

	Primary Dataset(s)	Data form(s)	Data variable(s)	Algorithm
No. subjects randomized	primaryanaldata			
No. adjudicated responders at wk 34 (%):	primaryanaldata	(FUSYM)	GRA_adjudicated	
Markedly improved				
Moderately improved				
Outcome changes from baseline to wk 34:				
No. subjects with complete data*				
Mean 24-hr frequency ± SD	voidlog_orig_p1	VOID	VOIDLG02	n_seq = number of voids recorded
Mean functional capacity (cc) ± SD†	voidlog_orig_p1	VOID	VOIDLG02	max_voidvol = maximum of nonmissing void volumes for the subject over 24 hours
Mean pain score ± SD (0–9)†	fusym_derived_p1	FUSYM	FUS1	
Mean urgency score ± SD (0–9)†	fusym_derived_p1	FUSYM	FUS2	
Mean O'Leary-Sant IC Symptom Index (0–20) ± SD	sym_derived_p1	SYM	SYMSCR	
Mean O'Leary-Sant IC Problem Index (0–16) ± SD	sym_derived_p1	SYM	PROBSCR	
Mean Wisconsin IC Symptom Inventory (0–42) ± SD	wis_derived_p1	WIS	WIS1, WIS2, WIS10, WIS18, WIS21, WIS23, WIS25	wisbladder: if nmiss(wis1, wis2, wis10, wis18, wis21, wis23, wis25)=0 then wisbladder = sum(wis1, wis2, wis10, wis18, wis21, wis23, wis25) ; excludes any subject with one or more missing items.

* Mean values for the analysis of secondary outcomes were based on only those subjects who had complete data for all points, excluding withdrawals and those with missing data. The sample sizes shown are slightly smaller for some secondary outcomes due to missing values. The p values are based on longitudinal regression models which included all available data up to the time of withdrawal. These results do not represent an intent to treat analysis and should be interpreted cautiously due to the potential bias in withdrawal from study. Also, no adjustment was made for the multiple comparisons and p values should be interpreted accordingly.

† Sample sizes for the functional bladder capacity were 113 for placebo and 109 for BCG.

Table D. DSIC results for Table 2 of Mayer et al (2005), "Efficacy outcomes by treatment arm".

Bolded entries disagree with published results; unbolded entries agree within rounding.

DSIC #1 uses all available subjects at baseline and week 34 for each secondary outcome. All DSIC #1 results agree with published results, except for mean functional capacity.

DSIC #2 uses, within each group of secondary outcomes (void frequency and volume, pain and urgency scores, O'Leary-Sant IC symptom and problem indexes, and Wisconsin IC symptom inventory), subjects with a form at baseline and each follow-up time point. DSIC #2 results agree (within rounding) with published results for mean functional capacity, but agreement varies otherwise.

	Placebo							BCG						
	Published	DSIC #1			DSIC #2			Published	DSIC #1			DSIC #2		
	Mean ± SD or n (%)	N	Mean or n	SD or %	N	Mean or n	SD or %	Mean ± SD or n (%)	N	Mean or n	SD or %	N	Mean or n	SD or %
No. subjects randomized	134		134					131		131				
No. adjudicated responders at wk 34 (%):	16 (12)		16	11.94				27 (21)		16	20.61			
Markedly improved	5		5					15		15				
Moderately improved	11		11					12		12				
Outcome changes from baseline to wk 34:														
No. subjects with complete data*	126							120						
Mean 24-hr frequency ± SD	-0.5 ± 9.7	122	-0.492	9.744	113	**-0.407**	**9.984**	-1.7 ± 8.0	117	-1.709	7.987	109	**-1.615**	**8.151**
Mean functional capacity (cc) ± SD† **[Note 1.]**	-17 ± 112	**122**	**-13.43**	**111.02**	113	-17.29	112.4	-26 ± 156	**117**	**-21.16**	**157.75**	109	-26.06	156.49
Mean pain score ± SD (0–9)	-0.9 ± 2.1	126	-0.909	2.121	123	**-0.967**	2.104	-1.4 ± 2.4	120	-1.442	2.433	118	-1.386	2.409
Mean urgency score ± SD (0–9)	-0.9 ± 2.0	126	-0.933	1.986	123	**-0.972**	1.992	-1.5 ± 2.3	120	-1.529	2.323	118	-1.479	2.309
Mean O'Leary-Sant IC Symptom Index (0–20) ± SD	-1.4 ± 3.5	**127**	-1.37	3.475	124	-1.371	3.507	-2.1 ± 4.4	120	-2.142	4.395	116	-2.069	4.359
Mean O'Leary-Sant IC Problem Index (0–16) ± SD	-1.7 ± 3.3	**127**	-1.654	3.281	124	-1.710	3.295	-2.3 ± 4.3	120	-2.267	4.252	116	**-2.198**	**4.229**
Mean Wisconsin IC Symptom Inventory (0–42) ± SD	-4.6 ± 9.2	**127**	-4.598	9.151	124	**-4.710**	9.225	-7.2 ± 11.4	119	-7.227	11.39	116	**-7.095**	**11.469**

* Mean values for the analysis of secondary outcomes were based on only those subjects who had complete data for all points, excluding withdrawals and those with missing data. The sample sizes shown are slightly smaller for some secondary outcomes due to missing values. The p values are based on longitudinal regression models which included all available data up to the time of withdrawal. These results do not represent an intent to treat analysis and should be interpreted cautiously due to the potential bias in withdrawal from study. Also, no adjustment was made for the multiple comparisons and p values should be interpreted accordingly.

† Sample sizes for the functional bladder capacity were 113 for placebo and 109 for BCG.

Note 1. Functional capacity here is synonymous with the label "max 24-hr voided vol" in Mayer et al (2005) Table 1. However, here, according to the data center, the maximum of nonmissing voids was used for each subject (whereas Mayer et al Table 1 excludes subjects with any missing void volumes).

References

1. Mayer R, Propert KJ, Peters KM, Payne CK, Zhang Y, Burks D, Culkin DJ, Diokno A, Hanno P, Landis JR, Madigan R, Messing EM, Nickel JC, Sant GR, Warren J, Wein AJ, Kusek JW, Nyberg LM, Foster HE, and The Interstitial Cystitis Clinical Trials Group (ICCTG). **A randomized controlled trial of intravesical bacillus Calmette-Guerin for treatment refractory interstitial cystitis.** J Urol 173(4):1186-91, 2005.

ATTACHMENT 1

Full Text of Article

Mayer R, Propert KJ, Peters KM, Payne CK, Zhang Y, Burks D, Culkin DJ, Diokno A, Hanno P, Landis JR, Madigan R, Messing EM, Nickel JC, Sant GR, Warren J, Wein AJ, Kusek JW, Nyberg LM, Foster HE, and The Interstitial Cystitis Clinical Trials Group (ICCTG). **A randomized controlled trial of intravesical bacillus Calmette-Guerin for treatment refractory interstitial cystitis.** J Urol 173(4):1186-91, 2005.

ATTACHMENT 2

SAS Code for Tabulations from the IBDGC-BCG Datasets in the NIDDK Repository

Reproduced below are SAS code ICCTG01.sas and ICCTG02a.sas, with filedates 6/8/2008 and 12/3/2008, respectively. These programs perform various data checks and explorations and reproduce descriptive statistics for Tables 1 and 2, respectively, in Mayer et al. (2005).

```
1
2   ********************************************************************************************************
3   ******************
4   Filename: ICCTG01.sas
5   Location: \\10.128.242.40\niddk\05_Users\Matt\ICCTG\SAS\ICCTG01.sas
6   Project: NIDDK repository
7   Author: Matt Koch
8   --------------------------------------------------------------------------------------------------------
9   ------------------
10  Description:  Descriptive analyses to replicate Table 1, Baseline Characteristics by Treatment
11  Arm,
12                of Mayer et al (2005), "A Randomized Controlled Trial of Intravesical Bacillus
13  Calmette-Guerin
14                for Treatment Refractory Interstitial Cystities, J Urol 173:1186-1191
15  --------------------------------------------------------------------------------------------------------
16  ------------------
17  Input: SAS Files:
18     \\10.128.242.40\niddk\03_Data_And_Tools\Studies\ICCTG_BCG\ICCTG_BCG_Data
19
20  Output:
21     \\10.128.242.40\niddk\05_Users\Matt\ICCTG\SAS\ICCTG01.rtf
22
23  --------------------------------------------------------------------------------------------------------
24  ------------------
25  Program History:
26
27    Date           Author               Modification
28    -----------    -----------------    ------------------------------------------------------------
29  ---------
30    04/30/2008     Matt Koch            Initial program
31
32  --------------------------------------------------------------------------------------------------------
33  ------------------
34  Notes:
35  ********************************************************************************************************
36  ********************;
37  *Libraries where data is located;
38  *libname bcg "\\10.128.242.40\niddk\03_Data_And_Tools\Studies\ICCTG_BCG\ICCTG_BCG_Data";
39  libname bcg "C:\Documents and Settings\dmakoc\My Documents\_Project - offline
40  copies\NIDDK\03_Data_And_Tools\Studies\ICCTG_BCG\ICCTG_BCG_Data";
41
42  libname library "C:\Documents and Settings\dmakoc\My Documents\_Project - offline
43  copies\NIDDK\Matt\ICCTG\SAS" ;
44
45  options orientation=portrait number nodate;
46
47  ods noproctitle;
48  *ods rtf file="\\10.128.242.40\niddk\05_Users\Matt\ICCTG\SAS\ICCTG01.rtf"
49      style=custom bodytitle startpage=off;
50  ods rtf file="C:\Documents and Settings\dmakoc\My Documents\_Project - offline
51  copies\NIDDK\Matt\ICCTG\SAS\ICCTG01.rtf"
52      style=custom bodytitle startpage=off;
53  ods graphics on ;
54
55  * Input and sort primaryanaldata ;
56  data primaryanaldata ; set bcg.primaryanaldata ; run ;
```

```
proc sort data = primaryanaldata; by subj ; run ;

* Check data structure for primaryanaldata ;
proc freq data=primaryanaldata ;
   tables ccid * arm ;
title1 "ICCTG BCG Study" ;
title2 "Check data structure for primaryanaldata" ;
run ;

* Input and sort SYM (O'Leary-Sant) data ;
data sym ; set bcg.sym_derived_p1 ; run ;
proc sort data=sym ; by subj ccid vnum ; run ;

* Check data structure for SYM data ;
proc freq data=sym;
   tables ccid*vnum ;
title1 "ICCTG BCG Study" ;
title2 "Check data structure for SYM" ;
run ;

* Input and sort WIS data ;
data wis ; set bcg.wis_derived_p1 ; run ;
proc sort data = wis ; by subj ccid vnum ; run ;

* Check data structure for WIS data ;
proc freq data=sym;
   tables ccid*vnum ;
title1 "ICCTG BCG Study" ;
title2 "Check data structure for WIS" ;
run ;

* Derive wisbladder score ;
data wis ;
   set wis ;
   if nmiss(of wis1-wis25)=0 then wissum = sum(of wis1-wis25) ;
   if nmiss(wis1, wis2, wis10, wis18, wis21, wis23, wis25)=0 then
      wisbladder = sum(wis1, wis2, wis10, wis18, wis21, wis23, wis25) ;
run ;

* Check Visit 2 distributions of items on U Wisc Sx Survey;
proc means data=wis ;
   where vnum = 2 ;
   var wis1-wis25 wissum wisbladder ;
title1 "ICCTG BCG Study" ;
title2 "check Visit 2 distributions of items on U Wisc Sx Survey" ;
run ;

* Input and sort VOIDLOG data, select visit 2 ;
data voidlog_v2 ; set bcg.voidlog_orig_p1 ; if vnum = 2 ; run ;
proc sort data = voidlog_v2 ; by subj ccid vnum seqno ; run ;

* Check distribution of voids volumes for visit 2 ;
proc means data = voidlog_v2 maxdec = 3 ;
   var voidlg02 ;
title1 "ICCTG BCG Study" ;
title2 "Check distribution of voids volumes for visit 2" ;
```

```
113  run ;
114
115  * Derive VOIDLOG summary vars for visit 2
116       - total number of voids during the 24-hour period,
117       - average volume per void during the 24-hour period,
118       - max void volume during the 24-hour period ;
119  proc means data = voidlog_v2 noprint n mean max ;
120     by subj ;
121     var seqno voidlg02 ;
122     output out = voidlog_v2_summ
123        n = n_seq n_voidvol
124        nmiss = nmiss_seq nmiss_voidvol
125        mean = mean_seq mean_voidvol
126        max = max_seq max_voidvol ;
127  run ;
128
129  proc print data = voidlog_v2 (obs = 30) ;
130  title1 "ICCTG BCG Study" ;
131  title2 "Print voidlog_v2 (obs=30)" ;
132  run ;
133
134  proc print data = voidlog_v2_summ (obs = 30) ;
135  title1 "ICCTG BCG Study" ;
136  title2 "Print voidlog_v2_summ (obs=30)" ;
137  run ;
138
139  data problem01 ;
140     set voidlog_v2_summ ;
141     if nmiss_seq > 0 | nmiss_voidvol > 0 ;
142  run ;
143
144  proc print data = problem01 ;
145  title1 "ICCTG BCG Study" ;
146  title2 "Print problem01 data - subjects with missing values for one or more voids" ;
147  run ;
148
149  data problem01a ;
150     merge problem01 (in=inprob01) voidlog_v2 ;
151     by subj ;
152     if inprob01 ;
153  run ;
154
155  proc print data = problem01a ;
156  title1 "ICCTG BCG Study" ;
157  title2 "Print problem01a data - all voids for subjects with missing values for one or more voids"
158  ;
159  run ;
160
161  proc means data = voidlog_v2_summ n nmiss mean std min max maxdec = 3;
162  title1 "ICCTG BCG Study" ;
163  title2 "Overall PROC MEANS on voidlog_v2_smmm" ;
164  run ;
165
166  * first set of results for voids didn't agree with Table 1, so ... ;
167  * set ave and max void volume to missing for 3 subjects that had missing values for one or more
168  voids ;
```

```
169  data voidlog_v2_summ ;
170     set voidlog_v2_summ ;
171      if nmiss_voidvol > 0 then do ;
172         mean_voidvol = . ;
173         max_voidvol = . ;
174      end ;
175  run ;
176
177  * select baseline visit ;
178  data sym2 ; set sym ; if vnum = 2 ; run ;
179  data wis2 ; set wis ; if vnum = 2 ; run ;
180
181
182  * assemble data for Table 1 ;
183  data table1 problem02 ;
184     merge bcg.primaryanaldata (in=inprim)
185           sym2 (in=insym2 keep=subj symscr probscr)
186           wis2 (in=inwis2 keep=subj wisbladder)
187           voidlog_v2_summ (in=invlsummv2 keep=subj n_seq n_voidvol mean_voidvol max_voidvol) ;
188     by subj ;
189     if (insym2 | inwis2 | invlsummv2) & not(inprim) then output problem02 ;
190     if dem3 in (1 4 6 98) then race2 = 98 ;
191      else race2 = dem3 ;
192     age = (vdate - dem1)/365.25/24/60/60 ;
193     agefloor = floor(age) ;
194     painsc = (bsym1_bsy1 + bsym2_bsy1)/2 ;
195     urgsc = (bsym1_bsy2 + bsym2_bsy2)/2 ;
196     output table1 ;
197  run ;
198
199  proc print data=problem02 ;
200  title1 "ICCTG BCG Study" ;
201  title2 "Print problem02 data - merge problem - not in primaryanaldata" ;
202  run ;
203
204  proc format ;
205     value gender
206        0="0:female"
207        1="1:male" ;
208     value race
209        1="1:Asian/Pac Isl  "
210        2="2:Black/AA"
211        3="3:Lat/Hisp/Mex-Am"
212        4="4:Native Am"
213        5="5:White/Cauc"
214        6="6:Multiracial"
215        98="98:Other" ;
216     value dursymp
217        1="0:<24w  "
218        2="1:24-52w"
219        3=">52w" ;
220  run ;
221
222  proc freq data=table1 ;
223     tables arm ;
224     tables (dem2 dem3 race2 bsym1_bsy4)* arm ;
```

```
225      format arm $arm. dem2 gender. dem3 race2 race. bsym1_bsy4 dursymp. ;
226   title1 "ICCTG BCG Study" ;
227   title2 "Analyses for Mayer et al (2005) Table 1" ;
228   run ;
229
230   proc means data=table1 n nmiss mean std min max maxdec = 3 ;
231      class arm ;
232      var age agefloor n_seq /*n_voidvol*/ mean_voidvol max_voidvol painsc urgsc symscr probscr
233   wisbladder ;
234      format arm $arm. ;
235   title1 "ICCTG BCG Study" ;
236   title2 "Analyses for Mayer et al (2005) Table 1" ;
237   run ;
238
239   ods rtf close;
240
```

```
1   ********************************************************************************************
2   *************************
3   Filename: ICCTG02a.sas
4   Location: \\10.128.242.40\niddk\05_Users\Matt\ICCTG\SAS\ICCTG02a.sas
5   Project: NIDDK repository
6   Author: Matt Koch
7   --------------------------------------------------------------------------------------------
8   ------------------------
9   Description:  Descriptive analyses to replicate Table 2, Efficacy Outcomes by Treatment
10  Arm,
11                of Mayer et al (2005), "A Randomized Controlled Trial of Intravesical
12  Bacillus Calmette-Guerin
13                for Treatment Refractory Interstitial Cystities, J Urol 173:1186-1191
14  --------------------------------------------------------------------------------------------
15  ------------------------
16  Input: SAS Files:
17     \\10.128.242.40\niddk\03_Data_And_Tools\Studies\ICCTG_BCG\ICCTG_BCG_Data
18
19  Output:
20     \\10.128.242.40\niddk\05_Users\Matt\ICCTG\SAS\ICCTG02a.rtf
21
22  --------------------------------------------------------------------------------------------
23  ------------------------
24  Program History:
25
26    Date           Author               Modification
27    -----------    -----------------    ------------------------------------------------
28  ---------------
29    12/3/2008      Matt Koch            Modified from ICCTG02.SAS - commented out from the
30  available data
31                                        analyses the routine to discard ave and max void
32  volumes if any void
33                                        volumes missing. Otherwise unchanged.
34
35  --------------------------------------------------------------------------------------------
36  ------------------------
37  Notes:
38  ********************************************************************************************
39  ***************************;
40  *Libraries where data is located;
41  *libname bcg "\\10.128.242.40\niddk\03_Data_And_Tools\Studies\ICCTG_BCG\ICCTG_BCG_Data";
42  libname bcg "C:\Documents and Settings\dmakoc\My Documents\_Project - offline
43  copies\NIDDK\03_Data_And_Tools\Studies\ICCTG_BCG\ICCTG_BCG_Data";
44
45  libname library "C:\Documents and Settings\dmakoc\My Documents\_Project - offline
46  copies\NIDDK\Matt\ICCTG\SAS" ;
47
48  options orientation=portrait number nodate;
49
50  ods noproctitle;
51  *ods rtf file="\\10.128.242.40\niddk\05_Users\Matt\ICCTG\SAS\ICCTG02a.rtf"
52      style=custom bodytitle startpage=off;
53  ods rtf file="C:\Documents and Settings\dmakoc\My Documents\_Project - offline
54  copies\NIDDK\Matt\ICCTG\SAS\ICCTG02a.rtf"
55      style=custom bodytitle startpage=off;
56  ods graphics on ;
```

```
57
58  ********************************************************** ;
59  ** GRA (global response assessment) - descriptive statistics ;
60  ********************************************************** ;
61
62  proc format ;
63     value nmiss
64        0-high = 1 ;
65  run ;
66
67  * Input and sort primaryanaldata ;
68  data primaryanaldata ; set bcg.primaryanaldata ; run ;
69  proc sort data = primaryanaldata; by subj ; run ;
70
71  * Check GRA vs GRA_adjudicated ;
72  proc freq data=primaryanaldata ;
73     tables GRA*GRA_adjudicated
74            arm*GRA*GRA_adjudicated ;
75  format arm $arm. ;
76  title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
77  title2 "primaryanaldata: check GRA vs GRA_adjudicated" ;
78  run ;
79
80  * Input and sort original GRA data from FUSYM form, Visit 15 (Week 34);
81  data fusym ; set bcg.fusym_derived_p1 ; if vnum = 15 ; run ;
82  proc sort data=fusym ; by subj ; run ;
83
84  * Merge primaryanaldata and FUSYM data;
85  data table2 problem1 ;
86     merge primaryanaldata (in=inprim keep=subj arm ccid gra gra_adjudicated)
87           fusym (in=infusym) ;
88     by subj ;
89     if inprim ne infusym then output problem1 ;
90     output table2 ;
91  run ;
92
93  * Print merge problems ;
94  proc print data = problem1 ;
95  title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
96  title2 "Problem1: problems with merge of primaryanaldata and fusym data" ;
97  run ;
98
99  * Formats for GRA raw data ;
100 proc format ;
101    value fus6_
102       1="1:markedly worse"
103       2="2:moderately worse"
104       3="3:slightly worse"
105       4="4:no change"
106       5="5:slightly improved"
107       6="6:moderately improved"
108       7="7:markedly improved" ;
109 run ;
110
111 * Check original GRA data from FUSYM form, Visit 15 (Week 34) ;
112 proc freq data=table2 ;
```

```
113       tables arm*fus6 / missing ;
114    format fus6 fus6_. ;
115    title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
116    title2 "fusym data: distribution of raw GRA data, Visit 15 (Week 34) by arm" ;
117    run ;
118
119    * compute GRA_derived from FUS6 (markedly or moderately improved, =0 if missing) ;
120    data table2 ;
121       set table2 ;
122       if fus6 ge 6 then GRA_derived = 1 ;
123        else GRA_derived = 0 ;
124    run ;
125
126    * check GRA variable vs GRA_derived ;
127    proc freq data = table2 ;
128       tables gra_derived*gra
129              arm*gra_derived*gra / missing ;
130    title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
131    title2 "Table2 data: distribution of GRA_derived by arm" ;
132    run ;
133
134    * subset disagreements between GRA_derived and GRA ;
135    data problem2 ;
136       set table2 ;
137       if gra_derived ne gra ;
138    run ;
139
140    * print disagreements between GRA_derived and GRA ;
141    proc print data = problem2 ;
142    title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
143    title2 "Table2 data: disagreements between GRA_derived and GRA " ;
144
145    * Check GRA_derived vs GRA_adjudicated ;
146    proc freq data=Table2 ;
147       tables GRA_derived*GRA_adjudicated
148              arm*GRA_derived*GRA_adjudicated ;
149    format arm $arm. ;
150    title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
151    title2 "Table2 data: check GRA_derived vs GRA_adjudicated" ;
152    run ;
153
154    * Check distribution of fus6 vs GRA_adjudicated ;
155    proc freq data = table2 ;
156       tables GRA_adjudicated*fus6
157              arm*GRA_adjudicated*fus6 / missing ;
158    format arm $arm. fus6 fus6_. ;
159    title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
160    title2 "Table2 data: distribution of fus6 vs GRA_adjudicated" ;
161    run ;
162
163    proc freq data = table2 ;
164       tables ccid*arm*GRA_adjudicated / cmh ;
165       exact comor ;
166    title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
167    title2 "Table2 data: exact CMH for distribution of arm vs GRA_adjudicated, controlling for
168    site" ;
```

```
169  run ;
170
171
172
173  ******************************************************************************** ;
174  ******************************************************************************** ;
175  ** Secondary outcomes (changes from baseline to wk 34) - descriptive statistics ;
176  ******************************************************************************** ;
177  ******************************************************************************** ;
178
179
180  ********************************************************************************************** ;
181  ** Voiding diary (VOID) data ;
182  ** 24-hour frequency and functional capacity ;
183  ** [NOTE: Although I can't find a definition in the paper, the protocol, or the MOO,
184  **  based on some web searching it appears that functional capacity in Table 2 is
185  **  analogous to max 24hour voided volume in Table 1.] ;
186  ********************************************************************************************** ;
187
188  * Input and sort VOIDLOG data ;
189  data voidlog ; set bcg.voidlog_orig_p1 ; run ;
190  proc sort data = voidlog ; by subj vnum seqno ; run ;
191
192  * Select visit 2 and visit 15 (week 34) data ;
193  data voidlog ;
194     set voidlog ;
195     if vnum = 2 or vnum = 15 ;
196  run ;
197
198  * Check distribution of voids volumes by visit ;
199  proc means data = voidlog maxdec = 3 ;
200     class vnum ;
201     var voidlg02 ;
202  title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
203  title2 "Check distribution of voids volumes by visit (visits 2 and 15)" ;
204  run ;
205
206  proc print data = voidlog (obs = 30) ;
207  title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
208  title2 "Print voidlog (obs=30) - visits 2 and 15" ;
209  run ;
210
211  * Derive VOIDLOG summary vars
212       - total number of voids during the 24-hour period,
213       - average volume per void during the 24-hour period,
214       - max void volume during the 24-hour period ;
215  proc means data = voidlog noprint n mean max ;
216     by subj vnum ;
217     var seqno voidlg02 ;
218     output out = voidlog_summ
219        n = n_seq n_voidvol
220        nmiss = nmiss_seq nmiss_voidvol
221        mean = mean_seq mean_voidvol
222        max = max_seq max_voidvol ;
223  run ;
224
```

```
225  proc print data = voidlog_summ (obs = 30) ;
226  title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
227  title2 "Print voidlog_summ (obs=30) - visits 2 and 15" ;
228  run ;
229
230  * Merge in treatment arm ;
231  data voidlog_summ ;
232     merge voidlog_summ (in=invoidlog)
233           primaryanaldata (keep=subj arm) ;
234     by subj ;
235     if invoidlog ;
236  run ;
237
238  * voidlog_summ - check counts of visit by arm, nonmissing outcomes by arm" ;
239  proc freq data = voidlog_summ ;
240     tables arm*vnum / missing ;
241     tables arm*(n_seq n_voidvol mean_voidvol max_voidvol) ;
242  format n_seq n_voidvol mean_voidvol max_voidvol nmiss. ;
243  title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
244  title2 "voidlog_summ - counts of visit by arm, nonmissing outcomes by arm" ;
245  run ;
246
247  data problem01 ;
248     set voidlog_summ ;
249     if nmiss_seq > 0 | nmiss_voidvol > 0 ;
250  run ;
251
252  proc print data = problem01 ;
253  title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
254  title2 "Print problem01 data - subjects with missing values for one or more voids - visits
255  2 and 15" ;
256  run ;
257
258  data problem01a ;
259     merge problem01 (in=inprob01) voidlog ;
260     by subj vnum ;
261     if inprob01 ;
262  run ;
263
264  proc print data = problem01a ;
265  title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
266  title2 "Print problem01a data - all voids for subjects with missing values for one or more
267  voids - visits 2 and 15" ;
268  run ;
269
270  proc means data = voidlog_summ n nmiss mean std min max maxdec = 3;
271     class vnum ;
272  title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
273  title2 "Overall PROC MEANS on voidlog_summ for visits 2 and 15" ;
274  run ;
275
276  /*
277  * [NOTE: first set of results for voids didn't agree with Table 1, so ...] ;
278  * set ave and max void volume to missing for subjects that had missing values for one or
279  more voids ;
280  data voidlog_summ ;
```

```
281      set voidlog_summ ;
282       if nmiss_voidvol > 0 then do ;
283          mean_voidvol = . ;
284          max_voidvol = . ;
285       end ;
286   run ;
287   */
288
289   * Make horizontal VOIDLOG summary file ;
290   data voidlog_land ;
291      set voidlog_summ ;
292      by subj vnum ;
293      retain n_seq_v2 n_voidvol_v2 mean_voidvol_v2 max_voidvol_v2
294             n_seq_v15 n_voidvol_v15 mean_voidvol_v15 max_voidvol_v15 ;
295      if first.subj then do ;
296         n_seq_v2 = . ;
297         n_seq_v15 = . ;
298         n_voidvol_v2 = . ;
299         n_voidvol_v15 = . ;
300         mean_voidvol_v2 = . ;
301         mean_voidvol_v15 = . ;
302         max_voidvol_v2 = . ;
303         max_voidvol_v15 = . ;
304      end ;
305      if vnum=2 then do ;
306         n_seq_v2 = n_seq ;
307         n_voidvol_v2 = n_voidvol ;
308         mean_voidvol_v2 = mean_voidvol ;
309         max_voidvol_v2 = max_voidvol ;
310      end ;
311      if vnum=15 then do ;
312         n_seq_v15 = n_seq ;
313         n_voidvol_v15 = n_voidvol ;
314         mean_voidvol_v15 = mean_voidvol ;
315         max_voidvol_v15 = max_voidvol ;
316      end ;
317      if last.subj then output ;
318      keep subj n_seq_v2 n_voidvol_v2 mean_voidvol_v2 max_voidvol_v2
319                n_seq_v15 n_voidvol_v15 mean_voidvol_v15 max_voidvol_v15 ;
320   run ;
321
322   proc print data = voidlog_land(obs=30) ;
323   title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
324   title2 "Print landscape voidlog data (obs=30)" ;
325   run;
326
327   * compute visit15 - visit2 differences for VOIDLOG summary variables ;
328   data voidlog_land ;
329      set voidlog_land ;
330         n_seq_change = n_seq_v15 - n_seq_v2 ;
331         n_voidvol_change = n_voidvol_v15 - n_voidvol_v2 ;
332         mean_voidvol_change = mean_voidvol_v15 - mean_voidvol_v2 ;
333         max_voidvol_change = max_voidvol_v15 - max_voidvol_v2 ;
334   run ;
335
336   * Merge VOIDLOG landscape data with primaryanaldata ;
```

```
337  data voidlog_land ;
338     merge primaryanaldata
339           voidlog_land ;
340     by subj ;
341  keep subj ccid arm n_seq_v2 n_voidvol_v2 mean_voidvol_v2 max_voidvol_v2
342                     n_seq_v15 n_voidvol_v15 mean_voidvol_v15 max_voidvol_v15
343                     n_seq_change n_voidvol_change mean_voidvol_change max_voidvol_change ;
344  run ;
345
346  * Check means and s.d.'s for VOIDLOG data ;
347  proc means data=voidlog_land n nmiss mean std min max maxdec = 3 ;
348     class arm ;
349     var n_seq_v2        n_seq_v15        n_seq_change
350         /* n_voidvol_v2    n_voidvol_v15    n_voidvol_change */
351         mean_voidvol_v2 mean_voidvol_v15 mean_voidvol_change
352         max_voidvol_v2  max_voidvol_v15  max_voidvol_change  ;
353     format arm $arm. ;
354  title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
355  title2 "Table2 data: distribution of VOIDLOG variables" ;
356  run ;
357
358
359  ******************************************************************************** ;
360  ** Baseline and follow-up symptom data - pain and urgency scores ;
361  ******************************************************************************** ;
362
363  * Input and sort primaryanaldata ;
364  data primaryanaldata ; set bcg.primaryanaldata ; run ;
365  proc sort data = primaryanaldata; by subj ; run ;
366
367  * Take mean (of visit 1 and visit 2) for baseline symptom pain and urgency variables ;
368  data primaryanaldata ;
369     set primaryanaldata ;
370     painsc = (bsym1_bsy1 + bsym2_bsy1)/2 ;
371     urgsc = (bsym1_bsy2 + bsym2_bsy2)/2 ;
372  run ;
373
374  * Input and sort pain (fus1) and urgency (fus2) from FUSYM form, Visit 15 (Week 34);
375  data fusym ; set bcg.fusym_derived_p1 ; if vnum = 15 ; run ;
376  proc sort data=fusym ; by subj ; run ;
377
378  * Merge baseline and week 34 pain and urgency data and take week34 - baseline differences
379  ;
380  data pain_urg ;
381     merge primaryanaldata
382           fusym ;
383     by subj ;
384     paindiff = fus1 - painsc ;
385     urgdiff = fus2 - urgsc ;
386  keep subj ccid arm painsc urgsc fus1 fus2 paindiff urgdiff ;
387  run ;
388
389  * Check means and s.d.'s for pain and urgency data ;
390  proc means data=pain_urg n nmiss mean std min max maxdec = 3 ;
391     class arm ;
392     var painsc urgsc fus1 fus2 paindiff urgdiff ;
```

```
393       format arm $arm. ;
394    title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
395    title2 "Table2 data: distribution of pain and urgency scores" ;
396    run ;
397
398    * T-tests for pain and urgency data (p-values in table are from longitudinal models) ;
399    proc ttest data = pain_urg ;
400       class arm ;
401       var paindiff urgdiff ;
402    title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
403    title2 "Table2 data: t-tests for pain and urgency scores" ;
404    run ;
405
406
407    ****************************************************************;
408    ** IC Symptom Index and Problem Index (O'Leary-Sant) (SYM) data ;
409    ****************************************************************;
410
411    * Input and sort SYM (O'Leary-Sant) data ;
412    data sym ; set bcg.sym_derived_p1 ; run ;
413    proc sort data=sym ; by subj vnum ; run ;
414
415    * Select visit 2 and visit 15 (week 34) data ;
416    data sym ;
417       set sym ;
418       if vnum = 2 or vnum = 15 ;
419    run ;
420
421    **(;
422
423    * Make horizontal SYM file ;
424    data sym_land ;
425       set sym ;
426       by subj vnum ;
427       retain symscr_v2 symscr_v15 probscr_v2 probscr_v15 ;
428       if first.subj then do ;
429          symscr_v2 = . ;
430          symscr_v15 = . ;
431          probscr_v2 = . ;
432          probscr_v15 = . ;
433       end ;
434       if vnum=2 then do ;
435          symscr_v2 = symscr ;
436          probscr_v2 = probscr ;
437       end ;
438       if vnum=15 then do ;
439          symscr_v15 = symscr ;
440          probscr_v15 = probscr ;
441       end ;
442       if last.subj then output ;
443       keep subj symscr_v2 symscr_v15 probscr_v2 probscr_v15 ;
444    run ;
445
446    * compute visit15 - visit2 difference for wisbladder score ;
447    data sym_land ;
448       set sym_land ;
```

```
449      symscr_change = symscr_v15 - symscr_v2 ;
450      probscr_change = probscr_v15 - probscr_v2 ;
451   run ;
452
453   * Merge SYM landscape data with primaryanaldata ;
454   data sym_land ;
455      merge primaryanaldata
456            sym_land ;
457      by subj ;
458   keep subj ccid arm symscr_v2 symscr_v15 symscr_change probscr_v2 probscr_v15
459   probscr_change ;
460   run ;
461
462   * Check means and s.d.'s for sym bladder data ;
463   proc means data=sym_land n nmiss mean std min max maxdec = 3 ;
464      class arm ;
465      var symscr_v2 symscr_v15 symscr_change probscr_v2 probscr_v15 probscr_change ;
466      format arm $arm. ;
467   title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
468   title2 "Table2 data: distribution of SYM (O'Leary-Sant) symptom and problem scores" ;
469   run ;
470
471
472   ***********************************************;
473   ** Wisconsin IC Symptom Inventory (WIS) data
474   ***********************************************;
475
476   * Input and sort WIS data ;
477   data wis ; set bcg.wis_derived_p1 ; run ;
478   proc sort data = wis ; by subj vnum ; run ;
479
480   * Derive wisbladder score ;
481   data wis ;
482      set wis ;
483      if nmiss(of wis1-wis25)=0 then wissum = sum(of wis1-wis25) ;
484      if nmiss(wis1, wis2, wis10, wis18, wis21, wis23, wis25)=0 then
485         wisbladder = sum(wis1, wis2, wis10, wis18, wis21, wis23, wis25) ;
486   run ;
487
488   * Select visit 2 and visit 15 (week 34) data ;
489   data wis ;
490      set wis ;
491      if vnum = 2 or vnum = 15 ;
492   run ;
493
494   * Mean and s.d. for wisbladder_change not same as in Table 2, so check for missing data ;
495   * [1 obs w/missing for one component, so fixed algorithm to make wisbladder=. ;
496   proc freq data = wis ;
497      tables wis1 wis2 wis10 wis18 wis21 wis23 wis25 wisbladder / missing ;
498   title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
499   title2 "Table2 data: check missing data in components of WIS bladder score" ;
500   run ;
501
502   * Make horizontal WIS file ;
503   data wis_land ;
504      set wis ;
```

```
505      by subj vnum ;
506      retain wisbladder_v2 wisbladder_v15 ;
507      if first.subj then do ;
508         wisbladder_v2 = . ;
509         wisbladder_v15 = . ;
510      end ;
511      if vnum=2 then wisbladder_v2 = wisbladder ;
512      if vnum=15 then wisbladder_v15 = wisbladder ;
513      if last.subj then output ;
514      keep subj wisbladder_v2 wisbladder_v15 ;
515   run ;
516
517   * compute visit15 - visit2 difference for wisbladder score ;
518   data wis_land ;
519      set wis_land ;
520      wisbladder_change = wisbladder_v15 - wisbladder_v2 ;
521   run ;
522
523   * Merge WIS landscape data with primaryanaldata ;
524   data wis_land ;
525      merge primaryanaldata
526            wis_land ;
527      by subj ;
528   keep subj ccid arm wisbladder_v2 wisbladder_v15 wisbladder_change ;
529   run ;
530
531   * Check means and s.d.'s for WIS bladder data ;
532   proc means data=wis_land n nmiss mean std min max maxdec = 3 ;
533      class arm ;
534      var wisbladder_v2 wisbladder_v15 wisbladder_change ;
535      format arm $arm. ;
536   title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
537   title2 "Table2 data: distribution of WIS bladder scores" ;
538   run ;
539
540
541
542
543
544   ********************************************************************** ;
545   ********************************************************************** ;
546   *** Check for obs w/all visits nonmissing and rerun descriptive stats ;
547   ********************************************************************** ;
548   ********************************************************************** ;
549
550   * Input and sort VOIDLOG data ;
551   data voidlog ; set bcg.voidlog_orig_p1 ; run ;
552   proc sort data = voidlog ; by subj vnum seqno ; run ;
553
554   * Derive VOIDLOG summary vars
555        - total number of voids during the 24-hour period,
556        - average volume per void during the 24-hour period,
557        - max void volume during the 24-hour period ;
558   proc means data = voidlog noprint n mean max ;
559      by subj vnum ;
560      var seqno voidlg02 ;
```

```
561      output out = voidlog_summ
562         n = n_seq n_voidvol
563         nmiss = nmiss_seq nmiss_voidvol
564         mean = mean_seq mean_voidvol
565         max = max_seq max_voidvol ;
566   run ;
567
568   proc print data = voidlog_summ (obs = 30) ;
569   title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
570   title2 "Print voidlog_summ (obs=30)" ;
571   run ;
572
573   data problem01 ;
574      set voidlog_summ ;
575      if nmiss_seq > 0 | nmiss_voidvol > 0 ;
576   run ;
577
578   proc print data = problem01 ;
579   title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
580   title2 "Print problem01 data - subjects with missing values for one or more voids" ;
581   run ;
582
583   /*
584   * [NOTE: first set of results for voids didn't agree with Table 1, so ...] ;
585   * set ave and max void volume to missing for subjects that had missing values for one or
586   more voids ;
587   data voidlog_summ ;
588      set voidlog_summ ;
589       if nmiss_voidvol > 0 then do ;
590          mean_voidvol = . ;
591          max_voidvol = . ;
592       end ;
593   run ;
594   */
595
596   * Make and merge visit number template before transposing data ;
597   data template_voidlog_summ ;
598      set primaryanaldata (keep = subj) ;
599      vnum = 2 ;  vnum_v = '_v2 ' ; output ;
600      vnum = 11 ; vnum_v = '_v11' ; output ;
601      vnum = 13 ; vnum_v = '_v13' ; output ;
602      vnum = 15 ; vnum_v = '_v15' ; output ;
603      return ;
604   run ;
605
606   * Merge visit number template with the voidlog_summ data ;
607   data voidlog_summ ;
608      merge voidlog_summ (in=indata)
609            template_voidlog_summ (in=intemplate);
610      by subj vnum ;
611      if not(indata) then voidlog_present = . ;
612        else voidlog_present = 1 ;
613   run ;
614
615   * Identify patients with one or more missing visits ;
616   proc means data = voidlog_summ noprint sum ;
```

```
617      by subj ;
618      var voidlog_present ;
619      output out = voidlog_count
620         sum = voidlog_count_sum ;
621   run ;
622
623   proc print data = voidlog_count (obs = 30) ;
624   title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
625   title2 "Table2 data: counts of nonmissing VOID forms (obs=30) " ;
626   run ;
627
628   proc freq data = voidlog_count ;
629      tables voidlog_count_sum / missing ;
630   title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
631   title2 "Table2 data: distribution of counts of nonmissing VOID forms (obs=30) " ;
632   run ;
633
634   proc print data = voidlog_summ (obs = 30) ;
635   title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
636   title2 "Table2 data: voidlog summary data merged with vnum template (obs=30) " ;
637   run ;
638
639   * Transpose data to get landscape file for each outcome ;
640   %macro transp (var) ;
641   proc transpose data = voidlog_summ out = voidlog_land_&var prefix=&var ;
642      by subj ;
643      var &var ;
644      id vnum_v ;
645   run ;
646   %mend transp ;
647
648   %transp (n_seq) ;
649   %transp (mean_voidvol) ;
650   %transp (max_voidvol) ;
651
652   * Merge the transposed files together ;
653   data voidlog_land ;
654      merge voidlog_land_n_seq
655            voidlog_land_mean_voidvol
656            voidlog_land_max_voidvol ;
657      by subj ;
658   run ;
659
660   proc print data = voidlog_land (obs = 30) ;
661   title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
662   title2 "Table2 data: check transposed voidlog summary data (obs=30)" ;
663   run ;
664
665   * Select only those subjects with complete data for all points ;
666   data voidlog_complete ;
667      set voidlog_count ;
668      if voidlog_count_sum = 4 ;
669   keep = subj ;
670   run ;
671
672   data voidlog_land ;
```

```
673      merge voidlog_land
674            voidlog_complete (in=in_voidlog_complete) ;
675      by subj ;
676      if in_voidlog_complete ;
677   run ;
678
679
680   * compute visit15 - visit2 differences for VOIDLOG summary variables ;
681   data voidlog_land ;
682      set voidlog_land ;
683         n_seq_change = n_seq_v15 - n_seq_v2 ;
684         mean_voidvol_change = mean_voidvol_v15 - mean_voidvol_v2 ;
685         max_voidvol_change = max_voidvol_v15 - max_voidvol_v2 ;
686   run ;
687
688   * Merge VOIDLOG landscape data with primaryanaldata ;
689   data voidlog_land ;
690      merge primaryanaldata
691            voidlog_land ;
692      by subj ;
693   keep subj ccid arm n_seq_v2 mean_voidvol_v2 max_voidvol_v2
694                      n_seq_v15 mean_voidvol_v15 max_voidvol_v15
695                      n_seq_change mean_voidvol_change max_voidvol_change ;
696   run ;
697
698   * Check means and s.d.'s for VOIDLOG data ;
699   proc means data=voidlog_land n nmiss mean std min max maxdec = 3 ;
700      class arm ;
701      var n_seq_v2        n_seq_v15        n_seq_change
702          mean_voidvol_v2 mean_voidvol_v15 mean_voidvol_change
703          max_voidvol_v2  max_voidvol_v15  max_voidvol_change  ;
704      format arm $arm. ;
705   title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
706   title2 "Table2 data: distribution of VOIDLOG variables" ;
707   title3 "ONLY SUBJECTS WITH VOIDLOG FORMS FOR ALL POINTS" ;
708   run ;
709
710   title3 ;
711
712
713
714   ********************************************************************************** ;
715   ** Baseline and follow-up symptom data - pain and urgency scores ;
716   ********************************************************************************** ;
717
718   * Input and sort primaryanaldata ;
719   data primaryanaldata ; set bcg.primaryanaldata ; run ;
720   proc sort data = primaryanaldata; by subj ; run ;
721
722   * Take mean (of visit 1 and visit 2) for baseline symptom pain and urgency variables, ;
723   *    name them fus1 and fus2 and create dummy vnum=0 for concatenating with f/u data ;
724   data primaryanaldata ;
725      set primaryanaldata ;
726      vnum = 0 ;
727      fus1 = (bsym1_bsy1 + bsym2_bsy1)/2 ;
728      fus2 = (bsym1_bsy2 + bsym2_bsy2)/2 ;
```

```
729  run ;
730
731  * Input and sort pain (fus1) and urgency (fus2) from FUSYM form ;
732  data fusym ; set bcg.fusym_derived_p1 (keep=subj vnum fus1 fus2) ; run ;
733  proc sort data=fusym ; by subj vnum ; run ;
734
735  * Concatenate primaryanaldata and fusym and sort ;
736  data fusym ;
737     set primaryanaldata (keep=subj vnum fus1 fus2)
738         fusym ;
739  run ;
740
741  proc sort data = fusym ; by subj vnum ; run ;
742
743  * Make and merge visit number template before transposing data ;
744  data template_fusym ;
745     set primaryanaldata (keep = subj) ;
746     vnum = 0 ;  vnum_v = '_v0 ' ;  output ;
747     vnum = 8 ;  vnum_v = '_v8 ' ;  output ;
748     vnum = 11 ; vnum_v = '_v11' ; output ;
749     vnum = 13 ; vnum_v = '_v13' ; output ;
750     vnum = 15 ; vnum_v = '_v15' ; output ;
751     return ;
752  run ;
753
754  proc print data = template_fusym (obs = 30) ;
755  title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
756  title2 "Table2 data: check visit number template data (obs=30)" ;
757  run ;
758
759  * Merge visit number template with FUSYM data ;
760  data fusym ;
761     merge fusym (in=indata)
762           template_fusym ;
763     by subj vnum ;
764     if not(indata) then fusym_present = . ;
765       else fusym_present = 1 ;
766  run ;
767
768  proc print data = fusym (obs = 30) ;
769  title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
770  title2 "Table2 data: FUSYM (with baseline) data merged with vnum template (obs=30) " ;
771  run ;
772
773  * Identify patients with one or more missing visits ;
774  proc means data = fusym noprint sum ;
775     by subj ;
776     var fusym_present ;
777     output out = fusym_count
778        sum = fusym_count_sum ;
779  run ;
780
781  proc print data = fusym_count (obs = 30) ;
782  title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
783  title2 "Table2 data: counts of nonmissing FUSYM (plus baseline) forms (obs=30) " ;
784  run ;
```

```
785
786   proc freq data = fusym_count ;
787      tables fusym_count_sum / missing ;
788   title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
789   title2 "Table2 data: distribution of counts of nonmissing FUSYM (plus baseline) forms
790   (obs=30) " ;
791   run ;
792
793   * Transpose data to get landscape file for each outcome ;
794   %macro transp (var) ;
795   proc transpose data = fusym out = fusym_land_&var prefix=&var ;
796      by subj ;
797      var &var ;
798      id vnum_v ;
799   run ;
800   %mend transp ;
801
802   %transp (fus1) ;
803   %transp (fus2) ;
804
805   * Merge the transposed files together ;
806   data fusym_land ;
807      merge fusym_land_fus1
808            fusym_land_fus2 ;
809      by subj ;
810   run ;
811
812   proc print data = fusym_land (obs = 30) ;
813   title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
814   title2 "Table2 data: check transposed FUSYM (plus baseline) data (obs=30)" ;
815   run ;
816
817   * Merge in arm and site from primaryanaldata ;
818   data fusym_land ;
819      merge fusym_land
820            primaryanaldata (keep = subj arm ccid) ;
821      by subj ;
822   run ;
823
824   * Check missing data patterns ;
825   proc freq data = fusym_land ;
826      tables arm*
827             fus1_v0*
828             fus1_v8*
829             fus1_v11*
830             fus1_v13*
831             fus1_v15
832         / list missing ;
833       tables arm*
834             fus2_v0*
835             fus2_v8*
836             fus2_v11*
837             fus2_v13*
838             fus2_v15
839         / list missing ;
840   format fus1_v0--fus1_v15 fus2_v0--fus2_v15 nmiss. ;
```

```
841  title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
842  title2 "Table2 data: check missing data patterns in transposed FUSYM (plus baseline) data"
843  ;
844  run ;
845
846  /*
847  * restrict analysis to subjects with complete data for sym (plus baseline) ;
848  data fusym_land ;
849     set fusym_land ;
850     if fus1_v0 ^=. and
851        fus1_v8 ^=. and
852        fus1_v11 ^=. and
853        fus1_v13 ^=. and
854        fus1_v15 ^=. and
855        fus2_v0 ^=. and
856        fus2_v8 ^=. and
857        fus2_v11 ^=. and
858        fus2_v13 ^=. and
859        fus2_v15 ^=. ;
860  run ;
861  */
862
863  * Select only those subjects with complete data for all points ;
864  data fusym_complete ;
865     set fusym_count ;
866     if fusym_count_sum = 5 ;
867  keep = subj ;
868  run ;
869
870  data fusym_land ;
871     merge fusym_land
872           fusym_complete (in=in_fusym_complete) ;
873     by subj ;
874     if in_fusym_complete ;
875  run ;
876
877  * compute visit15 - visit2 difference for pain (fus1) and urgency (fus2) scores ;
878  data fusym_land ;
879     set fusym_land ;
880     fus1_change = fus1_v15 - fus1_v0 ;
881     fus2_change = fus2_v15 - fus2_v0 ;
882  run ;
883
884  * Check means and s.d.'s for FUSYM (fus1) and urgency (fus2) scores  ;
885  * [NOTE: These means and s.d.'s do not all match the values in Table 2.] ;
886  proc means data=fusym_land n nmiss mean std min max maxdec = 3 ;
887     class arm ;
888     var fus1_v0 fus1_v15 fus1_change ;
889     var fus2_v0 fus2_v15 fus2_change ;
890     format arm $arm. ;
891  title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
892  title2 "Table2 data: distribution of FUSYM pain (fus1) and urgency (fus2)scores" ;
893  title3 "ONLY SUBJECTS WITH FUSYM (and baseline) FORMS FOR ALL POINTS" ;
894  run ;
895
896
```

```
897  ****************************************************************;
898  ** IC Symptom Index and Problem Index (O'Leary-Sant) (SYM) data ;
899  ****************************************************************;
900
901  * Input and sort SYM (O'Leary-Sant) data ;
902  data sym ; set bcg.sym_derived_p1 ; run ;
903  proc sort data=sym ; by subj vnum ; run ;
904
905  * Make and merge visit number template before transposing data ;
906  data template_sym ;
907     set primaryanaldata (keep = subj) ;
908     vnum = 2 ;  vnum_v = '_v2 ' ; output ;
909     vnum = 8 ;  vnum_v = '_v8' ;  output ;
910     vnum = 11 ; vnum_v = '_v11' ; output ;
911     vnum = 13 ; vnum_v = '_v13' ; output ;
912     vnum = 15 ; vnum_v = '_v15' ; output ;
913     return ;
914  run ;
915
916  proc print data = template_sym (obs = 30) ;
917  title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
918  title2 "Table2 data: check visit number template data (obs=30)" ;
919  run ;
920
921  * Merge visit number template with SYM data ;
922  data sym ;
923     merge sym (in=indata)
924           template_sym ;
925     by subj vnum ;
926     if not(indata) then sym_present = . ;
927       else sym_present = 1 ;
928  run ;
929
930  proc print data = sym (obs = 30) ;
931  title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
932  title2 "Table2 data: SYM data merged with vnum template (obs=30) " ;
933  run ;
934
935  * Identify patients with one or more missing visits ;
936  proc means data = sym noprint sum ;
937     by subj ;
938     var sym_present ;
939     output out = sym_count
940        sum = sym_count_sum ;
941  run ;
942
943  proc print data = sym_count (obs = 30) ;
944  title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
945  title2 "Table2 data: counts of nonmissing SYM forms (obs=30) " ;
946  run ;
947
948  proc freq data = sym_count ;
949     tables sym_count_sum / missing ;
950  title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
951  title2 "Table2 data: distribution of counts of nonmissing SYM forms (obs=30) " ;
952  run ;
```

```
953
954   * Transpose data to get landscape file for each outcome ;
955   %macro transp (var) ;
956   proc transpose data = sym out = sym_land_&var prefix=&var ;
957      by subj ;
958      var &var ;
959      id vnum_v ;
960   run ;
961   %mend transp ;
962
963   %transp (symscr) ;
964   %transp (probscr) ;
965
966   * Merge the transposed files together ;
967   data sym_land ;
968      merge sym_land_symscr
969            sym_land_probscr ;
970      by subj ;
971   run ;
972
973   proc print data = sym_land (obs = 30) ;
974   title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
975   title2 "Table2 data: check transposed SYM data (obs=30)" ;
976   run ;
977
978   * Merge in arm and site from primaryanaldata ;
979   data sym_land ;
980      merge sym_land
981            primaryanaldata (keep = subj arm ccid) ;
982      by subj ;
983   run ;
984
985   * Check missing data patterns ;
986   proc freq data = sym_land ;
987      tables arm*
988             symscr_v2*
989             symscr_v8*
990             symscr_v11*
991             symscr_v13*
992             symscr_v15
993         / list missing ;
994       tables arm*
995             probscr_v2*
996             probscr_v8*
997             probscr_v11*
998             probscr_v13*
999             probscr_v15
1000        / list missing ;
1001  format symscr_v2--symscr_v15 probscr_v2--probscr_v15 nmiss. ;
1002  title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
1003  title2 "Table2 data: check missing data patterns in transposed SYM data" ;
1004  run ;
1005
1006  /*
1007  * restrict analysis to subjects with complete data for symscr and probscr ;
1008  data sym_land ;
```

```
1009      set sym_land ;
1010      if symscr_v2 ^=. and
1011         symscr_v8 ^=. and
1012         symscr_v11 ^=. and
1013         symscr_v13 ^=. and
1014         symscr_v15 ^=. and
1015         probscr_v2 ^=. and
1016         probscr_v8 ^=. and
1017         probscr_v11 ^=. and
1018         probscr_v13 ^=. and
1019         probscr_v15 ^=.
1020         ;
1021   run ;
1022   */
1023
1024   * Select only those subjects with complete data for all points ;
1025   data sym_complete ;
1026      set sym_count ;
1027      if sym_count_sum = 5 ;
1028   keep = subj ;
1029   run ;
1030
1031   data sym_land ;
1032      merge sym_land
1033            sym_complete (in=in_sym_complete) ;
1034      by subj ;
1035      if in_sym_complete ;
1036   run ;
1037
1038   * compute visit15 - visit2 difference for symscr and probscr scores ;
1039   data sym_land ;
1040      set sym_land ;
1041      symscr_change = symscr_v15 - symscr_v2 ;
1042      probscr_change = probscr_v15 - probscr_v2 ;
1043   run ;
1044
1045   * Check means and s.d.'s for SYM symscr and probscr scores  ;
1046   * [NOTE: These means and s.d.'s do not all match the values in Table 2.] ;
1047   proc means data=sym_land n nmiss mean std min max maxdec = 3 ;
1048      class arm ;
1049      var symscr_v2 symscr_v15 symscr_change ;
1050      var probscr_v2 probscr_v15 probscr_change ;
1051      format arm $arm. ;
1052   title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
1053   title2 "Table2 data: distribution of SYM symscr and probscr scores" ;
1054   title3 "ONLY SUBJECTS WITH SYM FORMS FOR ALL POINTS" ;
1055   run ;
1056
1057
1058
1059   ***********************************************;
1060   ** Wisconsin IC Symptom Inventory (WIS) data
1061   ***********************************************;
1062
1063   * Input and sort WIS data ;
1064   data wis ; set bcg.wis_derived_p1 ; run ;
```

```
1065  proc sort data = wis ; by subj vnum ; run ;
1066
1067  * Derive wisbladder score ;
1068  data wis ;
1069     set wis ;
1070     if nmiss(wis1, wis2, wis10, wis18, wis21, wis23, wis25)=0 then
1071        wisbladder = sum(wis1, wis2, wis10, wis18, wis21, wis23, wis25) ;
1072  keep subj vnum wisbladder ;
1073  run ;
1074
1075  * Make and merge visit number template before transposing data ;
1076  data template_wis ;
1077     set primaryanaldata (keep = subj) ;
1078     vnum = 2 ;  vnum_v = '_v2 ' ; output ;
1079     vnum = 8 ;  vnum_v = '_v8' ;  output ;
1080     vnum = 11 ; vnum_v = '_v11' ; output ;
1081     vnum = 13 ; vnum_v = '_v13' ; output ;
1082     vnum = 15 ; vnum_v = '_v15' ; output ;
1083     return ;
1084  run ;
1085
1086  proc print data = template_wis (obs = 30) ;
1087  title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
1088  title2 "Table2 data: check visit number template data (obs=30)" ;
1089  run ;
1090
1091  * Merge visit number template with WIS data ;
1092  data wis ;
1093     merge wis (in=indata)
1094           template_wis ;
1095     by subj vnum ;
1096     if not(indata) then wis_present = . ;
1097       else wis_present = 1 ;
1098  run ;
1099
1100  proc print data = wis (obs = 30) ;
1101  title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
1102  title2 "Table2 data: WIS data merged with vnum template (obs=30) " ;
1103  run ;
1104
1105  * Identify patients with one or more missing visits ;
1106  proc means data = wis noprint sum ;
1107     by subj ;
1108     var wis_present ;
1109     output out = wis_count
1110        sum = wis_count_sum ;
1111  run ;
1112
1113  proc print data = wis_count (obs = 30) ;
1114  title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
1115  title2 "Table2 data: counts of nonmissing WIS forms (obs=30) " ;
1116  run ;
1117
1118  proc freq data = wis_count ;
1119     tables wis_count_sum / missing ;
1120  title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
```

```
1121  title2 "Table2 data: distribution of counts of nonmissing WIS forms (obs=30) " ;
1122  run ;
1123
1124
1125
1126  * Transpose data to get landscape file ;
1127  proc transpose data = wis out = wis_land prefix=wisbladder_v ;
1128     by subj ;
1129     var wisbladder ;
1130     id vnum ;
1131  run ;
1132
1133  proc print data = wis_land (obs = 30) ;
1134  title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
1135  title2 "Table2 data: check transposed WIS data (obs=30)" ;
1136  run ;
1137
1138  * Merge in arm and site from primaryanaldata ;
1139  data wis_land ;
1140     merge wis_land
1141           primaryanaldata (keep = subj arm ccid) ;
1142     by subj ;
1143  run ;
1144
1145  * Check missing data patterns ;
1146  proc freq data = wis_land ;
1147     tables arm*
1148            wisbladder_v2*
1149            wisbladder_v8*
1150            wisbladder_v11*
1151            wisbladder_v13*
1152            wisbladder_v15
1153         / list missing ;
1154  format wisbladder_v2--wisbladder_v15 nmiss. ;
1155  title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
1156  title2 "Table2 data: check missing data patterns in transposed WIS data" ;
1157  run ;
1158
1159  /*
1160  * restrict analysis to subjects with complete data for wisbladder ;
1161  data wis_land ;
1162     set wis_land ;
1163     if wisbladder_v2 ^=. and
1164        wisbladder_v8 ^=. and
1165        wisbladder_v11 ^=. and
1166        wisbladder_v13 ^=. and
1167        wisbladder_v15 ^=. ;
1168  run ;
1169  */
1170
1171  * Select only those subjects with complete data for all points ;
1172  data wis_complete ;
1173     set wis_count ;
1174     if wis_count_sum = 5 ;
1175  keep = subj ;
1176  run ;
```

```
1177
1178  data wis_land ;
1179     merge wis_land
1180           wis_complete (in=in_wis_complete) ;
1181     by subj ;
1182     if in_wis_complete ;
1183  run ;
1184
1185  * compute visit15 - visit2 difference for wisbladder score ;
1186  data wis_land ;
1187     set wis_land ;
1188     wisbladder_change = wisbladder_v15 - wisbladder_v2 ;
1189  run ;
1190
1191  * Check means and s.d.'s for WIS bladder  ;
1192  * [NOTE: These means and s.d.'s do not match the values in Table 2.] ;
1193  proc means data=wis_land n nmiss mean std min max maxdec = 3 ;
1194     class arm ;
1195     var wisbladder_v2 wisbladder_v15 wisbladder_change ;
1196     format arm $arm. ;
1197  title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
1198  title2 "Table2 data: distribution of WIS bladder scores" ;
1199  title3 "ONLY SUBJECTS WITH WIS FORMS FOR ALL POINTS" ;
1200  run ;
1201
1202
1203  * Check n's for complete data at all time points ;
1204  data complete_all_vis;
1205     merge primaryanaldata (keep=subj arm)
1206           voidlog_complete (in=in_voidlog_c)
1207           fusym_complete (in=in_fusym_c)
1208           sym_complete (in=in_sym_c)
1209           wis_complete (in=in_wis_c) ;
1210     by subj ;
1211  if in_voidlog_c & in_fusym_c & in_sym_c & in_wis_c ;
1212  run ;
1213
1214  proc freq data = complete_all_vis ;
1215     tables arm / missing ;
1216  title1 "ICCTG BCG Study, Mayer et al (2005) Table 2" ;
1217  title2 "Table2 data: # by arm for subjects with complete data for all points" ;
1218  title3 ;
1219
1220
1221
1222
1223  ods rtf close;
1224
1225
1226
```