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September 10, 2006
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Staff of the Biostatistical Coordinating Center (BCC) for MTOPS will not be able to complete their review of this document until later in the year. This memo is being released in DRAFT form with the understanding that revisions may be made when the BCC completes their review.

Integrity Check for MTOPS Baseline and Followup Files

As a partial check of the integrity of the MTOPS datasets archived in the NIDDK data repository, a set of tabulations was performed to verify that published results from the MTOPS study can be reproduced using the archived datasets. A small number of analyses were performed to duplicate published results for the baseline data and followup data reported by Medical Therapy of Prostatic Symptoms (MTOPS) Research Group in 2003 in the *New England Journal of Medicine (NEJM ,[2])* and in *Controlled Clinical Trials (CCT, [1]).* The results of this integrity check are described below.

Baseline Data. The MTOPS Research Group reports results for 3,047 (randomized) study participants of whom 116 were recruited during the pilot phase and 2,931 during the full study. Participants were randomly assigned to four treatments: placebo (737), Doxazosin (756), Finasteride (768), or a combination of Doxazosin and Finasteride (786). Eligibility criteria for the study included: (1) age of 50 or older, (2) American Urological Association (AUA) symptom score of 8 to 35 for subjects recruited in pilot phase and 8 to 30 for full study; (3) maximal urinary flow rate between 4 and 15 ml. per second with a voided volume of at least 125 ml (McConnell et al., 2003, p. 2388].

As a partial check of the integrity of the baseline dataset, a set of tabulations was performed to verify that both the reported overall sample characteristics and the distribution of cases across the experimental conditions [1, Table 1] can be reproduced using the archived baseline dataset. (A copy of the published tables and the full text of the 2003 NEJM and CCT articles can be found in Attachments 1 and 2. STATA 8/SE code and output for our baseline tabulations are included in Attachment 3.)

The table published by Bautista et al. in *CCT* breaks down the MTOPS sample by study phase and by treatment condition. Table 1 compares this published breakdown to results obtained from the dataset extracted from the archived SAS CIMPORT file *baseline.xpt.* As Table 1 shows, the counts obtained from the archived data match exactly the published tabulations. McConnell et al. have also published a tabulation of the race/ethnicity of study subjects together with means and standard deviations for seven other subject characteristics: age, AUA symptom score, prostate volume, maximal urinary flow rate, post-voiding residual volume, serum PSA, and serum creatinine.

Table 2 compares the race/ethnicity of subjects by treatment group as reported in McConnell et al. (2003) to the results obtained from tabulation of the archived baseline data. Again, the comparison yields a perfect match. Table 3 compares the means and standard deviations for seven metric variables both for all subjects and for each treatment condition. 34 of the 35 means (7 variables for 4 treatments plus totals) match exactly. The mean AUA symptom score for the Doxazosin condition, however, was calculated to be 17.13 while the published value was 17.6.[1] Since AUA scores are recorded for all 768 subjects in the archived database, this minor discrepancy should not be due to differences in treatment of missing data. Comparison of the 35 standard deviations show many very small discrepancies (some of which may be due to differences in rounding conventions). None of these discrepancies occur in tabulations for the total sample.

[1] Interestingly the published standard deviation (5.9) is close to the tabulated value (5.95).

Followup Data. The MTOPS Research Group also reports values over time for the incidence of various indicators of clinical progression of benign prostatic hyperplasia (BPH). As a check of the integrity of the followup datasets, we replicated (for each treatment group) the time-in-study calculations as well as the counts at four years of the cumulative occurrence of five outcomes: a 4-point rise in AUA symptom scores; acute urinary retention; incontinence; urinary tract infection or urosepsis; and invasive therapy due to BPH. These outcomes were assessed independently using both data from the reporting forms for "pre-defined events" (Forms E01-E03)[2] and the outcome reports of the Clinical Review Committee (CRC; Form R02). Table 4 compares results of our analyses of outcomes using the CRC database to the published trial results at four years. It will be seen from Table 4 that for AUA symptom score increases and the three urinary event outcomes, our results exactly match the published counts with one exception. The exception is reporting of urinary retention. In the Combination Therapy condition, we counted 3 occurrences of urinary retention while McConnell et al. (2003) report 4. For invasive therapies due to BPH, the counts match exactly for the placebo and Finasteride conditions. However, we counted 23 events in the Doxazosin condition and 10 in the Combination therapy condition while the published counts are 26 and 12. This discrepancy may be due to classification of some of the "other" reported therapies as "invasive therapy due for BPH". As Table 5 shows there were a substantial number of "other" therapies reported in the CRC database.

The details of our analyses and results are described below. (STATA 8/SE code and output for our tabulations from the followup dataset are included in Attachment 4).

Analyses. Our initial calculations assumed that the cumulative count of the number of events in the second panel of McConnell et al.'s Table 2 (labeled "at 4 yr") represented counts for men who had completed at least four years of followup visits. This inference was *mistakenly* drawn from the text statement that: "The four-year cumulative incidence (among the 75 percent of men who had at least four years of follow-up data) of overall clinical progression was 17 percent in the placebo group . . . (p. 2390)."

Working with the events and dates reported on the CRC reports and a variety of alternative ways of defining time in study,[3] we were never able to replicate the cumulative counts *"at 4 years"* in Table 2. Frustration ultimately led us to explore the initial reports of endpoint events (Forms E01, E02, and E03). Using the E-form variable that recorded weeks-in-study at the time of the event (e.g., AIVWK for reports of a 4-point AUA rises) and ignoring the length of the followup period, we discovered that we could finally match (with minor exceptions) the cumulative counts reported in the lower panel of Table 2. Re-analysis of the CCR report database ignoring length of followup and calculating a four-year period as 212 weeks (4 years plus 1 month),[4] we were able to almost perfectly replicate the counts of events reported in

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[2]Records of invasive therapies for BPH were not recorded in the E forms database.

[3]Calculations of endpoints were made using date of last Major FU visit, last standard FU visit, and the date recorded for last visit on form R10 for subjects who were lost to follow up. When no calculation of time-in-study using these alternates endpoints dates and dates of randomization allowed us to reproduce the numbers in Table 2, we explored alternate starting dates, e.g., date of screening visit 1, date of screening visit 2, etc. No permutation of start and end dates yielded a match of the counts of cumulative events reported in the lower panel of Table 2.

[4]We have queried the BCC for MTOPS concerning the additional month. (It is possible, for example, that medication was not begun until 4 weeks after randomization.)

Table 2. This calculation counts any event that occurred within 212 weeks after randomization regardless of whether the subject was followed for the entire four year period.

Calculation Details. To construct a dataset for these followup analyses, we proceeded through the following steps:

- Dates were calculated for the latest standard visit, latest major followup visit, and "last visit date" recorded on R10 form for subjects lost to followup.[5] Dates were calculated by separately merging data for all versions of forms F01(standard FU visit), F02 (major FU visit), and R10 (subjects lost to FU), sorting by IDNUM and date of visit, and selecting the latest date for each type of visit record. An overall date of "last visit" was then calculated for subsequent use[6] in calculating the length of the followup period. Files of last visit dates were saved for each type of visit record.

- Dates were then calculated for each of five target outcomes: (1) 4 pt. rise in AUA symptom scores, (2) invasive therapy for BPH, and (3–5) three urinary events — retention, incontinence, and urinary tract infection or urosepsis. Dates were extracted by repetitively merging data from all versions of the R02 clinical report datasets, selecting records for the target outcome using the WCLASS variable, sorting records by IDNUM and date of event, deleting all but the earliest record for each target outcome. Files of dates for each outcome were saved.

- The baseline dataset was then merged with the three datasets coding the dates of latest standard, major, and R-10 FU visits and the datasets recording the first dates of each target outcome. The merged data were then used to tabulate the number of target outcomes observed for each of four treatment conditions (placebo, Doxazosin, Finasteride, or combination of Doxazosin and Finasteride. The time intervals between dates of randomization and dates of occurrence of each outcome were then calculated. This interval was converted to weeks, and counts of target outcomes were calculated by time interval. Inspection of this tabulation revealed that use of an interval of 212 weeks (4 years plus 4 weeks) provided an almost exact match to published outcomes.

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[5]Six subjects were missing dates entries for all 3 variables. The ID numbers of these subjects are: 0235, 1131, 1670, 2320, and 2940. For our analysis, we assumed these subjects were loss to followup immediately after randmization, i.e., weeks in study was set to zero.

[6]Calculated as: (1) Date of last visit recorded on R10 form for persons lost to followup; otherwise: (2) Date of last major FU visit if that date was later than date of last standard FU visit or if the date of last standard FU visit was missing; or (2) Date of last standard FU visit if that date was later than date of last major FU visit or if the date of last major FU visit was missing. 6 cases had missing values for all three date variables. These cases were assumed to have a zero length of followup.

- As a check on these calculations, a parallel analysis was conducted using data for the forms employed for initial reporting of 4 of the 5 target events (E01, E03). This analysis yielded equivalent results with two exceptions.[7]

[7]One exception occurred for reporting of AUA score rise: Subject 2590 had a CCR record indicating a confirmed 4-point rise but there was no equivalent record in the E01 forms database. The second exception occurred for reporting of urinary events. Subject 2968 has a CCR report of a confirmed urinary event (incontinence), but there was no equivalent record in the E03 database.

References

Bautista OM, Kusek JW, Nyberg LM, McConnell JD, Bain RP, Miller G, Crawford ED, Kaplan SA, Sihelnik SA, Brawer MK, Lepor H. (2003) Study design of the Medical Therapy of Prostatic Symptoms (MTOPS) trial. *Controlled Clinical Trials,* 24(2):224-43.

McConnell JD, Roehrborn CG, Bautista OM, Andriole GL Jr, Dixon CM, Kusek JW, Lepor H, McVary KT, Nyberg LM Jr, Clarke HS, Crawford ED, Diokno A, Foley JP, Foster HE, Jacobs SC, Kaplan SA, Kreder KJ, Lieber MM, Lucia MS, Miller Menon M, Milam DF, Ramsdell JW, Schenkman NS, Slawin KM, Smith JA; Medical Therapy of Prostatic Symptoms (MTOPS) Research Group. (2003) The long-term effect of doxazosin, finasteride, and combination therapy on the clinical progression of benign prostatic hyperplasia. *New England Journal of Medicine,* 349(25):2387-98.

TABLE 1. Sample sizes in MTOPS trial by study phase and treatment condition: Comparison of Ns published by Bautista et al. (2003) and calculations from baseline data archived in NIDDK Repository.

BREAKDOWN	Published	Archive
By Study Phase		
Pilot	116	116
Full-Scale	2,931	2,931
TOTAL	3,047	3,047
By Treatment		
Placebo	737	737
Doxazosin	756	756
Finasteride	768	768
Combination	786	786
TOTAL	3,047	3,047

NOTE. Calculated from baseline dataset extracted from archived SAS CIMPORT file "baseline.xpt".

TABLE 2. Race-Ethnicity of subjects in MTOPS trial by treatment condition: Comparison of Ns published by McConnell et al. (2003, Table 1) and calculations from baseline data archived in NIDDK Repository.

	TREATMENT				
RACE / ETHNICITY	**Placebo**	**Doxazosin**	**Finasteride**	**Combination**	***TOTALS***
Published					
White	607	624	643	635	*2,509*
Black	67	65	61	77	*270*
Hispanic	52	57	47	67	*223*
Other	11	10	17	7	*45*
TOTALS	*737*	*756*	*768*	*786*	*3,047*
Calculated from archived data	607	624	643	635	*2,509*
Black	67	65	61	77	*270*
Hispanic	52	57	47	67	*223*
Other	11	10	17	7	*45*
TOTALS	*737*	*756*	*768*	*786*	*3,047*

NOTE. Calculated from baseline dataset extracted from archived SAS CIMPORT file "baseline.xpt".

TABLE 3. Means and standard for reported baseline characteristics of subjects in MTOPS trial by treatment condition: Comparison of statistics reported by McConnell et al. (2003, Table 1) and calculations from data archived in NIDDK Repository.

	Calculated from Archived Data			Published	
Variable	**N**	**Mean**	**SD**	**Mean**	**SD**
Total Sample					
Age, years	3047	62.614	7.327	62.6	7.3
AUA symptom score	3047	16.927	5.903	16.9	5.9
Prostate volume, ml	3041	36.321	20.112	36.3	20.1
Maximal urinary flow rate, ml/sec	3045	10.466	2.588	10.5	2.6
Post-void residual volume, ml	3041	68.097	82.924	68.1	82.9
Serum PSA, mg/ml	3047	2.359	2.083	2.4	2.1
Serum creatinine, mg/dl	3047	1.063	0.185	1.1	0.2
Placebo					
Age, years	737	62.514	7.580	62.5	7.5
AUA symptom score	737	16.830	5.981	16.8	5.9
Prostate volume, ml	737	35.159	18.889	35.2	18.8
Maximal urinary flow rate, ml/sec	737	10.452	2.661	10.5	2.6
Post-void residual volume, ml	735	69.620	82.137	69.6	82.1
Serum PSA, mg/ml	737	2.329	2.088	2.3	2.0
Serum creatinine, mg/dl	737	1.065	0.185	1.1	0.1
Doxazosin					
Age, years	756	62.722	7.300	62.7	7.2
AUA symptom score	756	16.952	5.8503	17.0	5.8
Prostate volume, ml	756	36.876	21.609	36.9	21.6
Maximal urinary flow rate, ml/sec	756	10.309	2.587	10.3	2.5
Post-void residual volume, ml	754	69.218	88.253	69.2	88.2
Serum PSA, mg/ml	756	2.408	2.166	2.4	2.1
Serum creatinine, mg/dl	756	1.062	0.171	1.1	0.1
Finasteride					
Age, years	768	62.551	7.328	62.6	7.3
AUA symptom score	768	17.132	5.951	**17.6**	5.9
Prostate volume, ml	765	36.854	20.608	36.9	20.6
Maximal urinary flow rate, ml/sec	768	10.511	2.568	10.5	2.5
Post-void residual volume, ml	767	66.168	80.085	66.2	80
Serum PSA, mg/ml	768	2.359	2.104	2.4	2.1
Serum creatinine, mg/dl	768	1.061	0.182	1.1	0.1
Combination					
Age, years	786	62.665	7.122	62.7	7.1
AUA symptom score	786	16.794	5.839	16.8	5.8
Prostate volume, ml	783	36.357	19.209	36.4	19.2
Maximal urinary flow rate, ml/sec	784	10.587	2.533	10.6	2.5
Post-void residual volume, ml	785	67.479	81.199	67.5	81.1
Serum PSA, mg/ml	786	2.341	1.977	2.3	1.9
Serum creatinine, mg/dl	786	1.065	0.199	1.1	0.1

NOTE. Calculated from baseline dataset extracted from archived SAS CIMPORT file "baseline.xpt". Variables used from archived baseline file were: age = Age years; qssadd = AUA symptom score; tugev = Prostate volume ml; vummxfr = Maximal urinary flow rate ml/sec; vumpvr = Post-void residual volume ml; yspsah = Serum PSA mg/ml; ssccre = Serum creatinine mg/dl.

TABLE 4. Cumulative counts of five outcomes in MTOPS trial by treatment condition: Comparison of countspublished by McConnell et al. (2003, Table 1) and calculations from data archived in NIDDK Repository. (Analysis limited to events observed within 212 weeks of randomization.)

RACE / ETHNICITY	TREATMENT			
	Placebo	**Doxazosin**	**Finasteride**	**Combination**
Published				
4 point or greater increase in AUA symptom score	97	55	65	36
Urinary retention	18	9	6	4
Incontinence	6	7	7	1
Urinary tract infection or urosepsis	1	2	0	1
Invasive therapy due to BPH	37	26	14	12
Calculated from archived data				
4 point or greater increase in AUA symptom score	97	55	65	36
Urinary retention	18	9	6	3
Incontinence	6	7	7	1
Urinary tract infection or urosepsis	1	2	0	1
Invasive therapy due to BPH	37	23	14	10

TABLE 5. Breakdown of "other" invasive therapies for BPH recorded in Clinical Review Report of MTOPS trial by treatment condition. (Analysis limited to therapies reported within 212 weeks of randomization.)

OTHER THERAPIES	TREATMENT			
	Placebo	Doxazosin	Finasteride	Combination
Bacillus Calmette-Guerrin (BCG)	0	0	1	1
Bladder Fulguration	0	0	1	0
External Beam Radiation	3	8	6	7
Orchiectomy	0	0	1	0
Radiation Seeds	8	5	5	6
Radical Cystectomy	0	0	0	1
Radiofrequency Treatment	0	1	0	0
Transurethral Resection of Bladder (TURBT)	2	2	1	3
Bladder and Prostate (TURBT/TURP)	0	2	0	1
Unknown	0	0	0	1

ATTACHMENT 1

"The full text of the article referenced will be provided to approved requestors along with the data archive."

Bautista OM, Kusek JW, Nyberg LM, McConnell JD, et al. (2003) Study design of the Medical Therapy of Prostatic Symptoms (MTOPS) trial. *Controlled Clinical Trials,* 24(2):224-43.

ATTACHMENT 2

"The full text of the article referenced will be provided to approved requestors along with the data archive."

McConnell JD, Roehrborn CG, Bautista OM, Andriole GL Jr, et al. (2003) The long-term effect of doxazosin, finasteride, and combination therapy on the clinical progression of benign prostatic hyperplasia. *New England Journal of Medicine,* 349(25):2387-98.

ATTACHMENT 3

STATA 8/SE Code and Output for *BASELINE* Tabulations from MTOPS Dataset in NIDDK Repository

```
      log:  P:\NIDDK\MTOPS\Baseline\Base_1.log
  log type:  text
 opened on:   6 Jun 2006, 12:02:45

. use "P:\NIDDK\MTOPS\Baseline\baseline_copy.dta", clear

. label define drug 1"Placebo" 2"Doxazosin" 3"Finasteride" 4"Combination"

. label values drug drug

. tab drug study

  treatment |   pilot/full scale
      group |         1          2 |     Total
------------+----------------------+----------
    Placebo |        27        710 |       737
  Doxazosin |        28        728 |       756
Finasteride |        29        739 |       768
Combination |        32        754 |       786
------------+----------------------+----------
      Total |       116      2,931 |     3,047


. describe age qssadd vummxfr tugev vumpvr yspsah

              storage  display     value
variable name   type   format      label      variable label
------------------------------------------------------------------------------
age             byte   %8.0g                  age at screening visit 1
qssadd          byte   %8.0g                  aua symptom score - q01
vummxfr         float  %9.0g                  uroflow-maximum flow rate - b03
tugev           float  %9.0g                  tot gland-ellipsoid volume - p01
vumpvr          int    %8.0g                  uroflow-post void residual - b03
yspsah          float  %9.0g                  psa - hybritech - d01

. summarize age qssadd vummxfr tugev vumpvr yspsah

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
         age |      3047    62.61405    7.327399         50         89
      qssadd |      3047    16.92714    5.903131          8         35
     vummxfr |      3045    10.46617     2.58756          4       15.3
       tugev |      3041    36.32068    20.11169        6.1        185
      vumpvr |      3041    68.09701    82.92447          0        789
-------------+--------------------------------------------------------
      yspsah |      3047     2.35914    2.083365         .2       10.5

. centile tugev

                                                      -- Binom. Interp. --
    Variable |     Obs  Percentile      Centile        [95% Conf. Interval]
-------------+-------------------------------------------------------------
       tugev |    3041         50            31            30.2        31.7
```

```
. summarize age qssadd vummxfr tugev vumpvr yspsah if drug == 1

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
         age |       737    62.51425    7.580017         50         89
      qssadd |       737    16.83039    5.980925          8         30
     vummxfr |       737     10.4517    2.661241          4         15
       tugev |       737    35.15875    18.88913        8.1        181
      vumpvr |       735    69.62041    82.13675          0        535
-------------+--------------------------------------------------------
      yspsah |       737    2.329172    2.088375         .2         10

. centile tugev if drug==1

                                                      -- Binom. Interp. --
    Variable |     Obs  Percentile      Centile        [95% Conf. Interval]
-------------+-------------------------------------------------------------
       tugev |     737         50          30.6              29        31.6

.
end of do-file

. log close
       log:  P:\NIDDK\MTOPS\Baseline\Base_1.log
  log type:  text
 closed on:   6 Jun 2006, 12:03:09
```

Replicate McConnell et al. (2003, Table 1)

```
      log:  P:\NIDDK\MTOPS\Baseline\Base_2.log
  log type:  text
 opened on:   6 Jun 2006, 13:29:26

. use "P:\NIDDK\MTOPS\Baseline\baseline_copy.dta", clear

. label define drug 1"Placebo" 2"Doxazosin" 3"Finasteride" 4"Combination"

. label values drug drug

. label define race_eth1 1"White" 2"Black" 3"Asian" 4"Hispanic" 5"Native
American"

. label values sgirace race_eth1

.
. generate race_eth = sgirace

. replace race_eth=3 if sgirace == 4
(223 real changes made)

. replace race_eth=4 if sgirace == 3
(41 real changes made)

. replace race_eth=4 if sgirace == 5
(4 real changes made)

. label define race_eth2 1"White" 2"Black" 3"Hispanic" 4"Other"

. label values race_eth race_eth2

.
. tab race_eth sgirace

           |                        race - b02
  race_eth |     White      Black      Asian   Hispanic  Native Am |     Total
-----------+--------------------------------------------------------+----------
     White |     2,509          0          0          0          0 |     2,509
     Black |         0        270          0          0          0 |       270
  Hispanic |         0          0          0        223          0 |       223
     Other |         0          0         41          0          4 |        45
-----------+--------------------------------------------------------+----------
     Total |     2,509        270         41        223          4 |     3,047


. tab race_eth drug, row

+----------------+
| Key            |
|----------------|
|   frequency    |
| row percentage |
+----------------+
```

```
           |                treatment group
  race_eth |   Placebo  Doxazosin  Finasteri  Combinati |     Total
-----------+--------------------------------------------+----------
     White |       607        624        643        635 |     2,509
           |     24.19      24.87      25.63      25.31 |    100.00
-----------+--------------------------------------------+----------
     Black |        67         65         61         77 |       270
           |     24.81      24.07      22.59      28.52 |    100.00
-----------+--------------------------------------------+----------
  Hispanic |        52         57         47         67 |       223
           |     23.32      25.56      21.08      30.04 |    100.00
-----------+--------------------------------------------+----------
     Other |        11         10         17          7 |        45
           |     24.44      22.22      37.78      15.56 |    100.00
-----------+--------------------------------------------+----------
     Total |       737        756        768        786 |     3,047
           |     24.19      24.81      25.21      25.80 |    100.00

. tab drug study

  treatment |   pilot/full scale
      group |         1          2 |     Total
------------+----------------------+----------
    Placebo |        27        710 |       737
  Doxazosin |        28        728 |       756
Finasteride |        29        739 |       768
Combination |        32        754 |       786
------------+----------------------+----------
      Total |       116      2,931 |     3,047
. sort drug
. describe age qssadd vummxfr tugev vumpvr yspsah ssccre

              storage  display     value
variable name   type   format      label      variable label
------------------------------------------------------------------------------
age             byte   %8.0g                  age at screening visit 1
qssadd          byte   %8.0g                  aua symptom score - q01
vummxfr         float  %9.0g                  uroflow-maximum flow rate - b03
tugev           float  %9.0g                  tot gland-ellipsoid volume - p01
vumpvr          int    %8.0g                  uroflow-post void residual - b03
yspsah          float  %9.0g                  psa - hybritech - d01
ssccre          float  %9.0g                  ser chem-creatinine - b02

. summarize age qssadd vummxfr tugev vumpvr yspsah ssccre

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
         age |      3047    62.61405    7.327399         50         89
      qssadd |      3047    16.92714    5.903131          8         35
     vummxfr |      3045    10.46617     2.58756          4       15.3
       tugev |      3041    36.32068    20.11169        6.1        185
      vumpvr |      3041    68.09701    82.92447          0        789
-------------+--------------------------------------------------------
      yspsah |      3047     2.35914    2.083365         .2       10.5
      ssccre |      3047     1.06321    .1845705         .1          2
```

```
. centile age qssadd vummxfr tugev vumpvr yspsah ssccre

                                                          -- Binom. Interp. --
    Variable |     Obs  Percentile      Centile        [95% Conf. Interval]
-------------+-------------------------------------------------------------
         age |    3047         50            62              62          63
      qssadd |    3047         50            17              16          17
     vummxfr |    3045         50          10.6            10.4        10.7
       tugev |    3041         50            31            30.2        31.7
      vumpvr |    3041         50            39              37          42
      yspsah |    3047         50           1.6             1.5         1.6
      ssccre |    3047         50             1               1         1.1

. by drug: summarize age qssadd vummxfr tugev vumpvr yspsah ssccre

-------------------------------------------------------------------------------
-> drug = Placebo

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
         age |       737    62.51425    7.580017        50         89
      qssadd |       737    16.83039    5.980925         8         30
     vummxfr |       737     10.4517    2.661241         4         15
       tugev |       737    35.15875    18.88913       8.1        181
      vumpvr |       735    69.62041    82.13675         0        535
-------------+--------------------------------------------------------
      yspsah |       737    2.329172    2.088375        .2         10
      ssccre |       737    1.064586    .1852059        .1        1.9

-------------------------------------------------------------------------------
-> drug = Doxazosin

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
         age |       756    62.72222    7.299974        50         85
      qssadd |       756    16.95238     5.85026         8         30
     vummxfr |       756    10.30913    2.587153       4.2         15
       tugev |       756    36.87593    21.60929       6.1      155.6
      vumpvr |       754    69.21751    88.25317         0        789
-------------+--------------------------------------------------------
      yspsah |       756    2.407937    2.166351        .2         10
      ssccre |       756    1.062169    .1713911        .6          2

-------------------------------------------------------------------------------
-> drug = Finasteride

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
         age |       768    62.55078    7.327861        50         83
      qssadd |       768    17.13151    5.950876         8         30
     vummxfr |       768    10.51146    2.568031       4.1         15
       tugev |       765    36.85386    20.60795       9.3      170.3
      vumpvr |       767    66.16819    80.08525         0        694
-------------+--------------------------------------------------------
      yspsah |       768    2.358724    2.104134        .2       10.5
      ssccre |       768    1.061068    .1817126        .4        1.7

-------------------------------------------------------------------------------
-> drug = Combination

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
         age |       786    62.66539    7.121601        50         84
      qssadd |       786    16.79389     5.83866         8         35
     vummxfr |       784    10.58686    2.533307       4.1       15.3
       tugev |       783    36.35734    19.20915         7        185
```

```
      vumpvr |       785    67.47898    81.19863          0        517
-------------+--------------------------------------------------------
      yspsah |       786    2.340712     1.97731         .2        9.7
      ssccre |       786    1.065013    .1987472         .2        1.9

. by drug: centile age qssadd vummxfr tugev vumpvr yspsah ssccre

-------------------------------------------------------------------------------
-> drug = Placebo

                                                      -- Binom. Interp. --
    Variable |     Obs  Percentile      Centile        [95% Conf. Interval]
-------------+-------------------------------------------------------------
         age |     737          50            62              61          63
      qssadd |     737          50            17              16          17
     vummxfr |     737          50          10.6            10.3     10.7613
       tugev |     737          50          30.6              29        31.6
      vumpvr |     735          50            41              37          45
      yspsah |     737          50           1.5             1.4         1.7
      ssccre |     737          50           1.1               1         1.1

-------------------------------------------------------------------------------
-> drug = Doxazosin

                                                      -- Binom. Interp. --
    Variable |     Obs  Percentile      Centile        [95% Conf. Interval]
-------------+-------------------------------------------------------------
         age |     756          50            63              62          63
      qssadd |     756          50            17              16          17
     vummxfr |     756          50         10.35            10.1        10.6
       tugev |     756          50         31.15            29.7    32.74542
      vumpvr |     754          50            40              36          45
      yspsah |     756          50           1.6             1.4         1.7
      ssccre |     756          50           1.1               1         1.1

-------------------------------------------------------------------------------
-> drug = Finasteride

                                                      -- Binom. Interp. --
    Variable |     Obs  Percentile      Centile        [95% Conf. Interval]
-------------+-------------------------------------------------------------
         age |     768          50            62              61          63
      qssadd |     768          50            17              16          18
     vummxfr |     768          50          10.5            10.3    10.76656
       tugev |     765          50            31            29.5          33
      vumpvr |     767          50            39        33.85968          45
      yspsah |     768          50           1.5             1.4         1.7
      ssccre |     768          50             1               1         1.1

-------------------------------------------------------------------------------
-> drug = Combination

                                                      -- Binom. Interp. --
    Variable |     Obs  Percentile      Centile        [95% Conf. Interval]
-------------+-------------------------------------------------------------
         age |     786          50            63              62          63
      qssadd |     786          50            16              16          17
     vummxfr |     784          50          10.7            10.5          11
       tugev |     783          50          31.4            30.1        32.8
      vumpvr |     785          50            39              35    44.46607
      yspsah |     786          50           1.6             1.5         1.7
      ssccre |     786          50             1               1         1.1

.
.
```

```
end of do-file
```

ATTACHMENT 4

STATA 8/SE Code and Output for *FOLLOWUP* Tabulations from MTOPS Dataset in NIDDK Repository

```
      log:  C:\NIDDK\MTOPS\Integrity\Analysis\FU_Analyses.log
  log type:  text
 opened on:   5 Jul 2006, 08:24:51

.
. * QUESTION: Why do we have 6 cases without dates for Major, Std, or Record 10 dates
?
.
. ***                                                                          ***
. *** FIRST, get dates for last visit for Major FU, Standard FU,               ***
. ***              date recorded on R10 form for last visit if lost to FU,     ***
. ***              PLUS date of Screening Visits 1 and 2                       ***
. ***                                                                          ***
.
. *** 1-A  Date of Last STANDARD Follow Up                                     ***
.
. use "C:\NIDDK\MTOPS\SAS db\F Forms\F01\FILES\f011.dta", clear

. merge using "C:\NIDDK\MTOPS\SAS db\F Forms\F01\FILES\f012.dta"
fviwk was byte now int
fcmcona was str23 now str29
fcmconc was str24 now str27
fcmcond was str23 now str32
fcmcone was str39 now str47

. drop _merge

. merge using "C:\NIDDK\MTOPS\SAS db\F Forms\F01\FILES\f013.dta"
fcmcona was str29 now str36
fcmconc was str27 now str47
fcmcond was str32 now str39
fcmconf was str27 now str39
fcmcong was str28 now str47
fcmconi was str17 now str33
fcmconj was str18 now str47
fumtmf was byte now int

. drop _merge

. merge using "C:\NIDDK\MTOPS\SAS db\F Forms\F01\FILES\f014.dta"
fcmcond was str39 now str47

. drop _merge

. sort idnum fvstdt

. generate IDnext = idnum[_n +1]
(1 missing value generated)

. replace  IDnext = "9999" if _n ==_N
(1 real change made)

. drop if  idnum == IDnext
(26655 observations deleted)

.
. rename fvstdt StdFU_Date

. label var StdFU_Date "Date of last Standard FU Visit"

. rename fviwk StdFU_Week

. label var StdFU_Week "Week of last Standard FU Visit"
```

```
. keep idnum StdFU_Date StdFU_Week

. sort idnum

. describe , short

Contains data from C:\NIDDK\MTOPS\SAS db\F Forms\F01\FILES\f011.dta
  obs:         2,933
 vars:             3
 size:        41,062 (99.9% of memory free)
Sorted by:  idnum
     Note:  dataset has changed since last saved

. save "C:\NIDDK\MTOPS\Integrity\Analysis\LastStdFU.dta", replace
file C:\NIDDK\MTOPS\Integrity\Analysis\LastStdFU.dta saved

.
.
. *** 1-B Date of Last Major Follow Up
***
.
. use "C:\NIDDK\MTOPS\SAS db\F Forms\F02\FILES\f022.dta", clear

. merge using "C:\NIDDK\MTOPS\SAS db\F Forms\F02\FILES\f021.dta"

. drop _merge

. sort idnum jvstdt

. generate IDnext = idnum[_n +1]
(1 missing value generated)

. replace  IDnext = "9999" if _n ==_N
(1 real change made)

. drop if  idnum == IDnext
(9841 observations deleted)

. rename jvstdt MajorFU_Date

. label var MajorFU_Date "Date of last Major FU Visit"

. rename jviwk MajorFU_Week

. label var MajorFU_Week "Week of last Major FU Visit"

. keep idnum MajorFU_Date MajorFU_Week

. sort idnum

. describe , short

Contains data from C:\NIDDK\MTOPS\SAS db\F Forms\F02\FILES\f022.dta
  obs:         2,908
 vars:             3
 size:        40,712 (99.9% of memory free)
Sorted by:  idnum
     Note:  dataset has changed since last saved

. save "C:\NIDDK\MTOPS\Integrity\Analysis\LastMajorFU.dta", replace
file C:\NIDDK\MTOPS\Integrity\Analysis\LastMajorFU.dta saved

. * pause
```

```
.
. *** 1-C Date of Last Follow Up for Ss lost to FU from R10 form          ***
.
. use "C:\niddk\mtops\SAS db\R Forms\R10\FILES\r101.dta", clear

. rename svstdt LastVisit_R10record

. keep idnum LastVisit_R10record

. sort idnum

. describe , short

Contains data from C:\niddk\mtops\SAS db\R Forms\R10\FILES\r101.dta
  obs:           404
 vars:             2
 size:         4,848 (99.9% of memory free)
Sorted by:  idnum
     Note:  dataset has changed since last saved

. save "C:\NIDDK\MTOPS\Integrity\Analysis\Last_R10,dta", replace
file C:\NIDDK\MTOPS\Integrity\Analysis\Last_R10,dta.dta saved

.
.
. *** 1-D MERGE records for Major, Standard, R10FU Dates    ***
.
. use "C:\NIDDK\MTOPS\Integrity\Analysis\Last_R10,dta", clear

. sort idnum

. merge idnum using "C:\NIDDK\MTOPS\Integrity\Analysis\LastStdFU.dta"

. drop _merge

. sort idnum

. merge idnum using "C:\NIDDK\MTOPS\Integrity\Analysis\LastMajorFU.dta"

. drop _merge

. sort idnum

.
. describe , short

Contains data from C:\NIDDK\MTOPS\Integrity\Analysis\Last_R10,dta.dta
  obs:         3,041
 vars:             6                          5 Jul 2006 08:24
 size:        72,984 (99.9% of memory free)
Sorted by:  idnum
     Note:  dataset has changed since last saved

. save "C:\NIDDK\MTOPS\Integrity\Analysis\Visit_Dates.dta", replace
file C:\NIDDK\MTOPS\Integrity\Analysis\Visit_Dates.dta saved

.
. ***
                       ***
. *** SECOND, generate dates for OUTCOME events                          ***
. ***              Invasive Therapy, AUA 4 pt. rise from Baseline,           ***
. ***              Progression of BPH, Urinary Events
***
```

```
. ***
                        ***
.
. *** 2-A  MERGE the 5 versions of Clinical Review Record                    ***
.
. use "C:\NIDDK\MTOPS\SAS db\R Forms\R02\Files\r025.dta", clear

. append using "C:\NIDDK\MTOPS\SAS db\R Forms\R02\Files\r021.dta"

. append using "C:\NIDDK\MTOPS\SAS db\R Forms\R02\Files\r022.dta"

. append using "C:\NIDDK\MTOPS\SAS db\R Forms\R02\Files\r023.dta"
wtnxox was str36 now str42

. append using "C:\NIDDK\MTOPS\SAS db\R Forms\R02\Files\r024.dta"

. tab vers

       form |
    version |      Freq.     Percent        Cum.
------------+-----------------------------------
          1 |          3        0.12        0.12
          2 |         36        1.47        1.59
          3 |         82        3.35        4.94
          4 |         62        2.53        7.47
          5 |      2,266       92.53      100.00
------------+-----------------------------------
      Total |      2,449      100.00

.
. label define endpoint 1 "Death" 2 "AUA rise" 3"Creat Rise" 4"Urinary Evt"
5"NonCompl" 6"Inactive FU" 7"Invasive Rx" 8"
> Xover Open Label Rx"

. label define types 0"None" 1"Retention" 2"U Infection" 3"Incontinence"

. label values wuetyp types

. label values wclass endpoint

. tab1 wclass wuetyp

-> tabulation of wclass

 classification for |
            patient |      Freq.     Percent        Cum.
--------------------+-----------------------------------
               Death |        127        5.19        5.19
           AUA rise |        275       11.23       16.41
       Urinary Evt |         77        3.14       19.56
          NonCompl |      1,139       46.51       66.07
       Inactive FU |        324       13.23       79.30
       Invasive Rx |        256       10.45       89.75
Xover Open Label Rx |        251       10.25      100.00
--------------------+-----------------------------------
              Total |      2,449      100.00

-> tabulation of wuetyp

urin-type of |
       event |      Freq.     Percent        Cum.
-------------+-----------------------------------
   Retention |         41       53.25       53.25
```

```
 U Infection |          5        6.49       59.74
Incontinence |         31       40.26      100.00
-------------+-----------------------------------
       Total |         77      100.00

.
. ***
. *** ---> NOTE, no confirmed creatinine rise events <---
. ***
.
. generate AUArise_1=wssiev - wssbas
(2174 missing values generated)

. generate AUArise_2=wsscev - wssbas
(2174 missing values generated)

. tab1 AUArise_1 AUArise_2

-> tabulation of AUArise_1

  AUArise_1 |      Freq.     Percent        Cum.
------------+-----------------------------------
          4 |         56       20.36       20.36
          5 |         54       19.64       40.00
          6 |         41       14.91       54.91
          7 |         36       13.09       68.00
          8 |         25        9.09       77.09
          9 |         15        5.45       82.55
         10 |         13        4.73       87.27
         11 |         13        4.73       92.00
         12 |          5        1.82       93.82
         13 |          6        2.18       96.00
         14 |          2        0.73       96.73
         15 |          3        1.09       97.82
         16 |          3        1.09       98.91
         17 |          2        0.73       99.64
         18 |          1        0.36      100.00
------------+-----------------------------------
      Total |        275      100.00

-> tabulation of AUArise_2

  AUArise_2 |      Freq.     Percent        Cum.
------------+-----------------------------------
          4 |         72       26.18       26.18
          5 |         49       17.82       44.00
          6 |         47       17.09       61.09
          7 |         22        8.00       69.09
          8 |         27        9.82       78.91
          9 |         19        6.91       85.82
         10 |          9        3.27       89.09
         11 |         13        4.73       93.82
         12 |          5        1.82       95.64
         13 |          3        1.09       96.73
         14 |          3        1.09       97.82
         16 |          1        0.36       98.18
         17 |          1        0.36       98.55
         19 |          3        1.09       99.64
         21 |          1        0.36      100.00
------------+-----------------------------------
      Total |        275      100.00

. describe , short
```

```
Contains data from C:\NIDDK\MTOPS\SAS db\R Forms\R02\Files\r025.dta
  obs:         2,449
 vars:            70
 size:     1,089,805 (99.7% of memory free)
Sorted by:
     Note:  dataset has changed since last saved

. save "C:\NIDDK\MTOPS\Integrity\Analysis\R02_merged.dta", replace
file C:\NIDDK\MTOPS\Integrity\Analysis\R02_merged.dta saved

.
.
. *** 2-B  Get Date of DEATH
      ***
.
. drop if wclass ~= 1
(2322 observations deleted)

. tab wclass

 classification for |
            patient |      Freq.     Percent        Cum.
--------------------+-----------------------------------
              Death |        127      100.00      100.00
--------------------+-----------------------------------
              Total |        127      100.00

. generate death=1

. rename wddate D_date

. keep idnum death D_date

. sort idnum

. describe , short

Contains data from C:\NIDDK\MTOPS\Integrity\Analysis\R02_merged.dta
  obs:           127
 vars:             3                          5 Jul 2006 08:24
 size:         2,032 (99.9% of memory free)
Sorted by:  idnum
     Note:  dataset has changed since last saved

. save "C:\NIDDK\MTOPS\Integrity\Analysis\deaths.dta", replace
file C:\NIDDK\MTOPS\Integrity\Analysis\deaths.dta saved

.
. *** 2-C Get Date of AUA Score rise
  ***
.
. use "C:\NIDDK\MTOPS\Integrity\Analysis\R02_merged.dta", clear

. drop if wclass ~= 2
(2174 observations deleted)

. tab wclass

 classification for |
            patient |      Freq.     Percent        Cum.
--------------------+-----------------------------------
           AUA rise |        275      100.00      100.00
--------------------+-----------------------------------
```

```
             Total |        275      100.00

. generate AUA=1

. rename wssevdt AUA_date

. keep idnum AUA AUA_date

. *
. * Keep ONLY the first event
. *
. sort idnum AUA_date

. generate IDprevious = idnum[_n -1]
(1 missing value generated)

. replace  IDprevious = "9999" if _n ==1
(1 real change made)

. drop if  idnum == IDprevious
(1 observation deleted)

. describe , short

Contains data from C:\NIDDK\MTOPS\Integrity\Analysis\R02_merged.dta
  obs:           274
 vars:             4                          5 Jul 2006 08:24
 size:         5,480 (99.9% of memory free)
Sorted by:  idnum  AUA_date
     Note:  dataset has changed since last saved

. save "C:\NIDDK\MTOPS\Integrity\Analysis\AUA.dta", replace
file C:\NIDDK\MTOPS\Integrity\Analysis\AUA.dta saved

.
. *** 2-B  Get Date of CREATININE Rise
    ***
.
. use "C:\NIDDK\MTOPS\Integrity\Analysis\R02_merged.dta", clear

. drop if wclass ~= 3
(2449 observations deleted)

. tab wclass
no observations

. generate CRrise=1

. rename wcriev CR_date

. *
. * Keep ONLY the first event
. *
. keep idnum CRrise CR_date

. sort idnum CR_date

. generate IDprevious = idnum[_n -1]

. replace  IDprevious = "9999" if _n ==1
(0 real changes made)

. drop if  idnum == IDprevious
```

```
(0 observations deleted)

. describe , short

Contains data from C:\NIDDK\MTOPS\Integrity\Analysis\R02_merged.dta
  obs:             0
 vars:             4                          5 Jul 2006 08:24
 size:             0 (100.0% of memory free)
Sorted by:  idnum  CR_date
     Note:  dataset has changed since last saved

. save "C:\NIDDK\MTOPS\Integrity\Analysis\CR.dta", replace
(note: dataset contains 0 observations)
file C:\NIDDK\MTOPS\Integrity\Analysis\CR.dta saved

.
. *** 2-B  Get Date of URINARY EVENT
     ***
.
. use "C:\NIDDK\MTOPS\Integrity\Analysis\R02_merged.dta", clear

. drop if wclass ~= 4
(2372 observations deleted)

. tab wclass

 classification for |
            patient |      Freq.     Percent        Cum.
--------------------+-----------------------------------
        Urinary Evt |         77      100.00      100.00
--------------------+-----------------------------------
              Total |         77      100.00

. generate URevent=1

. rename  wueevdt UR_date

. rename  wuetyp UR_Type

. label values UR_Type types

. keep idnum URevent UR_Type UR_date

. *
. * Keep ONLY the first event
. * BUT make sure that we haven't dropped multiple TYPES
. *
. tab UR_Type

urin-type of |
       event |      Freq.     Percent        Cum.
-------------+-----------------------------------
   Retention |         41       53.25       53.25
 U Infection |          5        6.49       59.74
Incontinence |         31       40.26      100.00
-------------+-----------------------------------
       Total |         77      100.00

. sort idnum UR_date

. generate IDprevious = idnum[_n -1]
(1 missing value generated)
```

```
. replace  IDprevious = "9999" if _n ==1
(1 real change made)

. drop if  idnum == IDprevious
(0 observations deleted)

. tab UR_Type

urin-type of |
       event |      Freq.     Percent        Cum.
-------------+-----------------------------------
   Retention |         41       53.25       53.25
 U Infection |          5        6.49       59.74
Incontinence |         31       40.26      100.00
-------------+-----------------------------------
       Total |         77      100.00

. describe , short

Contains data from C:\NIDDK\MTOPS\Integrity\Analysis\R02_merged.dta
  obs:            77
 vars:             5                          5 Jul 2006 08:24
 size:         1,617 (99.9% of memory free)
Sorted by:  idnum  UR_date
     Note:  dataset has changed since last saved

. save "C:\NIDDK\MTOPS\Integrity\Analysis\UR.dta", replace
file C:\NIDDK\MTOPS\Integrity\Analysis\UR.dta saved

.
. *** 2-B  Get Date of INVASIVE PROCEDURE
***
.
. use "C:\NIDDK\MTOPS\Integrity\Analysis\R02_merged.dta", clear

. drop if wclass ~= 7
(2193 observations deleted)

. tab1 wclass wctit

-> tabulation of wclass

 classification for |
            patient |      Freq.     Percent        Cum.
--------------------+-----------------------------------
        Invasive Rx |        256      100.00      100.00
--------------------+-----------------------------------
              Total |        256      100.00

-> tabulation of wctit

xover-speci |
fy invasive |
    therapy |      Freq.     Percent        Cum.
------------+-----------------------------------
          1 |         77       30.08       30.08
          2 |          5        1.95       32.03
          3 |         74       28.91       60.94
          4 |          7        2.73       63.67
          5 |          4        1.56       65.23
          6 |          8        3.13       68.36
          7 |          3        1.17       69.53
          9 |         78       30.47      100.00
```

```
------------+-----------------------------------
      Total |        256      100.00

.
. generate X_InvasiveRX=1

. rename  wctevdt XInvasive_date

. rename  wctit      XInvasive_type

. label define XInvasive_type 0"None" 1"TURP" 2"TUIP" 3"Radical Prstctmy" 4"Open
Prstctmy" 5"TUNA" 6"Microwave" 7"Laser"
>  8"Stent" 9"Other"

. label values XInvasive_type XInvasive_type

. keep idnum X_InvasiveRX XInvasive_date XInvasive_type wctitx

. *
. * Keep ONLY the first event
. *
. sort idnum XInvasive_date

. generate IDprevious = idnum[_n -1]
(1 missing value generated)

. replace  IDprevious = "9999" if _n ==1
(1 real change made)

. drop if  idnum == IDprevious
(4 observations deleted)

. describe , short

Contains data from C:\NIDDK\MTOPS\Integrity\Analysis\R02_merged.dta
  obs:           252
 vars:             6                          5 Jul 2006 08:24
 size:        17,640 (99.9% of memory free)
Sorted by:  idnum  XInvasive_date
     Note:  dataset has changed since last saved

. save "C:\NIDDK\MTOPS\Integrity\Analysis\XInvasive.dta", replace
file C:\NIDDK\MTOPS\Integrity\Analysis\XInvasive.dta saved

.
.
*******************************************************************************
*****
. ***
  ***
. ***  THIRD, merge these EVENT DATE Files with BASELINE File and VISIT DATE Files
  ***
. ***
  ***
.
*******************************************************************************
*****
.
. use "C:\NIDDK\MTOPS\Baseline\baseline_copy.dta", clear

. sort idnum

. merge idnum using "C:\NIDDK\MTOPS\Integrity\Analysis\deaths.dta"
```

```
. replace death=0 if death==.
(2920 real changes made)

. drop _merge

.
. sort idnum

. merge idnum using "C:\NIDDK\MTOPS\Integrity\Analysis\AUA.dta"

. replace AUA=0 if AUA==.
(2773 real changes made)

. drop _merge

.
. sort idnum

. merge idnum using "C:\NIDDK\MTOPS\Integrity\Analysis\CR.dta"

. replace CRrise=0 if CRrise==.
(3047 real changes made)

. drop _merge

.
. sort idnum

. merge idnum using "C:\NIDDK\MTOPS\Integrity\Analysis\UR.dta"

. replace URevent =0 if URevent==.
(2970 real changes made)

. replace UR_Type=0 if URevent==0
(2970 real changes made)

. drop _merge

.
. sort idnum

. merge idnum using "C:\NIDDK\MTOPS\Integrity\Analysis\XInvasive.dta"

. label define drug 1"Placebo" 2"Doxazosin" 3"Finasteride" 4"Combination"

. label values drug drug

. replace X_InvasiveRX=0 if X_InvasiveRX==.
(2795 real changes made)

. replace XInvasive_type=0 if XInvasive_type==.
(2795 real changes made)

.
. drop _merge

.
. sort idnum

. merge idnum using "C:\NIDDK\MTOPS\Integrity\Analysis\Visit_Dates.dta"

. drop _merge
```

```
. sort idnum

. describe , short

Contains data from C:\NIDDK\MTOPS\Baseline\baseline_copy.dta
  obs:         3,047
 vars:           431
 size:     4,320,646 (98.6% of memory free)
Sorted by:  idnum
     Note:  dataset has changed since last saved

. save "C:\NIDDK\MTOPS\Integrity\Analysis\Base_FU_EVENTS.dta", replace
file C:\NIDDK\MTOPS\Integrity\Analysis\Base_FU_EVENTS.dta saved

.
. * tab1  death D_date  AUA AUA_date CRrise CR_date URevent UR_Type UR_date
. tab drug death, row

+----------------+
| Key            |
|----------------|
|   frequency    |
| row percentage |
+----------------+

  treatment |         death
      group |         0          1 |     Total
------------+----------------------+----------
    Placebo |       706         31 |       737
            |     95.79       4.21 |    100.00
------------+----------------------+----------
  Doxazosin |       734         22 |       756
            |     97.09       2.91 |    100.00
------------+----------------------+----------
Finasteride |       730         38 |       768
            |     95.05       4.95 |    100.00
------------+----------------------+----------
Combination |       750         36 |       786
            |     95.42       4.58 |    100.00
------------+----------------------+----------
      Total |     2,920        127 |     3,047
            |     95.83       4.17 |    100.00


. tab drug AUA, row

+----------------+
| Key            |
|----------------|
|   frequency    |
| row percentage |
+----------------+

  treatment |          AUA
      group |         0          1 |     Total
------------+----------------------+----------
    Placebo |       637        100 |       737
            |     86.43      13.57 |    100.00
------------+----------------------+----------
  Doxazosin |       697         59 |       756
            |     92.20       7.80 |    100.00
------------+----------------------+----------
Finasteride |       694         74 |       768
```

```
            |     90.36       9.64 |    100.00
------------+----------------------+----------
Combination |       745         41 |       786
            |     94.78       5.22 |    100.00
------------+----------------------+----------
      Total |     2,773        274 |     3,047
            |     91.01       8.99 |    100.00
```

```
. tab drug CRrise, row
```

```
+----------------+
| Key            |
|----------------|
|   frequency    |
| row percentage |
+----------------+
```

```
  treatment |   CRrise
      group |         0 |     Total
------------+-----------+----------
    Placebo |       737 |       737
            |    100.00 |    100.00
------------+-----------+----------
  Doxazosin |       756 |       756
            |    100.00 |    100.00
------------+-----------+----------
Finasteride |       768 |       768
            |    100.00 |    100.00
------------+-----------+----------
Combination |       786 |       786
            |    100.00 |    100.00
------------+-----------+----------
      Total |     3,047 |     3,047
            |    100.00 |    100.00
```

```
. tab drug UR_Type, row
```

```
+----------------+
| Key            |
|----------------|
|   frequency    |
| row percentage |
+----------------+
```

```
  treatment |             urin-type of event
      group |      None  Retention  U Infecti  Incontine |     Total
------------+-------------------------------------------+----------
    Placebo |       709         18          2          8 |       737
            |     96.20       2.44       0.27       1.09 |    100.00
------------+-------------------------------------------+----------
  Doxazosin |       730         13          2         11 |       756
            |     96.56       1.72       0.26       1.46 |    100.00
------------+-------------------------------------------+----------
Finasteride |       753          6          0          9 |       768
            |     98.05       0.78       0.00       1.17 |    100.00
------------+-------------------------------------------+----------
Combination |       778          4          1          3 |       786
            |     98.98       0.51       0.13       0.38 |    100.00
------------+-------------------------------------------+----------
      Total |     2,970         41          5         31 |     3,047
            |     97.47       1.35       0.16       1.02 |    100.00
```

```
. tab drug X_InvasiveRX, row

+----------------+
| Key            |
|----------------|
|   frequency    |
| row percentage |
+----------------+

  treatment |     X_InvasiveRX
      group |         0          1 |     Total
------------+----------------------+----------
    Placebo |       663         74 |       737
            |     89.96      10.04 |    100.00
------------+----------------------+----------
  Doxazosin |       683         73 |       756
            |     90.34       9.66 |    100.00
------------+----------------------+----------
Finasteride |       726         42 |       768
            |     94.53       5.47 |    100.00
------------+----------------------+----------
Combination |       723         63 |       786
            |     91.98       8.02 |    100.00
------------+----------------------+----------
      Total |     2,795        252 |     3,047
            |     91.73       8.27 |    100.00


.
. ***                                                          ***
. ***   Get LATEST date of Major FU, Standard FU, and R-10 FU  ***
. ***                                                          ***
.
. generate latest= 99

. replace  latest = 1 if MajorFU_Week > StdFU_Week
(2720 real changes made)

. replace  latest = 1 if MajorFU_Week == StdFU_Week
(120 real changes made)

. replace  latest = 2 if MajorFU_Week < StdFU_Week
(207 real changes made)

. replace  latest = 1 if MajorFU_Week~=. & StdFU_Week==.
(71 real changes made)

. replace  latest = 2 if MajorFU_Week==. & StdFU_Week~=.
(96 real changes made)

. replace  latest = 0 if MajorFU_Week==. & StdFU_Week==.  & LastVisit_R10record ==.
(6 real changes made)

. replace  latest = 3 if LastVisit_R10record ~=.
(404 real changes made)

. label var latest "Last visit"

. label define latest 1"Major FU" 2"Standard FU" 3"Record 10" 0"Missing All 3"

. label values latest latest
```

```
. tab latest

   Last visit |      Freq.     Percent        Cum.
--------------+-----------------------------------
Missing All 3 |          6        0.20        0.20
     Major FU |      2,555       83.85       84.05
  Standard FU |         82        2.69       86.74
    Record 10 |        404       13.26      100.00
--------------+-----------------------------------
        Total |      3,047      100.00
```

```
. list idnum latest rvstdt StdFU_Week MajorFU_Week  LastVisit_R10record if latest==0
```

	idnum	latest	rvstdt	StdFU_~k	MajorF~k	LastVi~d
235.	0235	Missing All 3	08 Mar 96	.	.	.
1131.	1131	Missing All 3	19 Jul 96	.	.	.
1670.	1670	Missing All 3	08 Apr 96	.	.	.
2320.	2320	Missing All 3	11 Dec 96	.	.	.
2338.	2338	Missing All 3	22 May 97	.	.	.
2940.	2940	Missing All 3	31 Jul 96	.	.	.

```
.
. *
. * Turn R10 date into WEEKS
. *
.
. generate R10_WeekFloat = (LastVisit_R10record - rvstdt)/7
(2643 missing values generated)

. generate R10_Week = round(R10_WeekFloat)
(2643 missing values generated)

. list idnum LastVisit_R10record rvstdt R10_Week if latest==3 & _n<100
```

	idnum	LastVis~d	rvstdt	R10_Week
28.	0028	17 Mar 97	14 Jun 96	39
29.	0029	14 Jun 01	22 Mar 96	273
42.	0042	10 Nov 97	13 May 96	78
43.	0043	23 Jun 97	04 Oct 96	37
45.	0045	25 Nov 97	26 Jun 96	74
50.	0050	20 Aug 01	07 Mar 96	285
55.	0055	07 Sep 00	05 Mar 98	131
64.	0064	07 Jun 01	20 Mar 97	220
67.	0067	30 Apr 01	01 Apr 96	265
68.	0068	28 Aug 01	19 Mar 97	232
72.	0072	13 Feb 97	23 May 96	38
80.	0080	09 Oct 00	26 Mar 96	237
94.	0094	10 Jul 98	17 Jul 96	103
97.	0097	31 Aug 01	13 Feb 97	237

```
. generate END = 9999

. replace  END = MajorFU_Week if latest==1
(2555 real changes made)
```

```
. replace  END = StdFU_Week if latest==2
(82 real changes made)

. replace  END = R10_Week if latest==3
(404 real changes made)

. list idnum latest rvstdt StdFU_Week StdFU_Date MajorFU_Week MajorFU_Week
LastVisit_R10record R10_Week if END==9999


+-------------------------------------------------------------------------------
-----------------+
      | idnum          latest      rvstdt   StdFU_~k   StdFU_~e   MajorF~k   MajorF~k
 LastVi~d   R10_Week |

|-------------------------------------------------------------------------------
-----------------|
 235. |  0235   Missing All 3   08 Mar 96          .          .          .          .
        .          . |
1131. |  1131   Missing All 3   19 Jul 96          .          .          .          .
        .          . |
1670. |  1670   Missing All 3   08 Apr 96          .          .          .          .
        .          . |
2320. |  2320   Missing All 3   11 Dec 96          .          .          .          .
        .          . |
2338. |  2338   Missing All 3   22 May 97          .          .          .          .
        .          . |

|-------------------------------------------------------------------------------
-----------------|
2940. |  2940   Missing All 3   31 Jul 96          .          .          .          .
        .          . |

+-------------------------------------------------------------------------------
-----------------+


.
. ** ASSUME NO FOLLOWUP IF NO MAJOR, STANDARD OR R10 RECORDS **
.
. replace  END = 0 if latest==0
(6 real changes made)

. generate END_collapsed = END

. replace  END_collapsed=1 if END>0 & END <100
(204 real changes made)

. replace  END_collapsed=100 if END>99 & END <200
(423 real changes made)

. replace  END_collapsed=225 if END>199 & END <300
(2282 real changes made)

. replace  END_collapsed=300 if END>299
(96 real changes made)

. label define END_collapsed 1"1-99" 100"100-199" 225"225-299" 300"300+"

. label values END_collapsed END_collapsed

. list idnum latest END END_collapsed StdFU_Week MajorFU_Week R10_Week if _n<51

     +-------------------------------------------------------------------+
```

	idnum	latest	END	END_co~d	StdFU_~k	MajorF~k	R10_Week
1.	0001	Major FU	263	225-299	156	263	.
2.	0002	Major FU	247	225-299	143	247	.
3.	0003	Major FU	260	225-299	158	260	.
4.	0004	Major FU	260	225-299	157	260	.
5.	0005	Major FU	210	225-299	114	210	.
6.	0006	Major FU	209	225-299	120	209	.
7.	0007	Major FU	259	225-299	181	259	.
8.	0008	Major FU	209	225-299	131	209	.
9.	0009	Major FU	265	225-299	194	265	.
10.	0010	Major FU	260	225-299	169	260	.
11.	0011	Major FU	208	225-299	116	208	.
12.	0012	Major FU	208	225-299	104	208	.
13.	0013	Major FU	261	225-299	181	261	.
14.	0014	Major FU	260	225-299	156	260	.
15.	0015	Major FU	235	225-299	130	235	.
16.	0016	Major FU	265	225-299	170	265	.
17.	0017	Major FU	169	100-199	117	169	.
18.	0018	Major FU	182	100-199	92	182	.
19.	0019	Major FU	195	100-199	90	195	.
20.	0020	Major FU	208	225-299	116	208	.
21.	0021	Major FU	210	225-299	103	210	.
22.	0022	Major FU	213	225-299	117	213	.
23.	0023	Major FU	197	100-199	104	197	.
24.	0024	Major FU	261	225-299	180	261	.
25.	0025	Major FU	222	225-299	131	222	.
26.	0026	Major FU	209	225-299	102	209	.
27.	0027	Major FU	288	225-299	182	288	.
28.	0028	Record 10	39	1-99	40	.	39
29.	0029	Record 10	273	225-299	195	260	273
30.	0030	Major FU	262	225-299	157	262	.
31.	0031	Major FU	286	225-299	181	286	.
32.	0032	Major FU	208	225-299	106	208	.
33.	0033	Major FU	210	225-299	119	210	.
34.	0034	Major FU	249	225-299	143	249	.
35.	0035	Major FU	210	225-299	183	210	.
36.	0036	Major FU	211	225-299	133	211	.
37.	0037	Major FU	209	225-299	130	209	.
38.	0038	Major FU	261	225-299	157	261	.
39.	0039	Standard FU	116	100-199	116	106	.
40.	0040	Major FU	261	225-299	195	261	.
41.	0041	Major FU	241	225-299	130	241	.
42.	0042	Record 10	78	1-99	65	52	78
43.	0043	Record 10	37	1-99	38	.	37
44.	0044	Major FU	235	225-299	129	235	.
45.	0045	Record 10	74	1-99	64	51	74
46.	0046	Major FU	205	225-299	103	205	.
47.	0047	Major FU	391	300+	286	391	.
48.	0048	Major FU	262	225-299	171	262	.
49.	0049	Major FU	233	225-299	130	233	.
50.	0050	Record 10	285	225-299	197	285	285

```
. tab latest

   Last visit |      Freq.     Percent        Cum.
--------------+-----------------------------------
Missing All 3 |          6        0.20        0.20
     Major FU |      2,555       83.85       84.05
  Standard FU |         82        2.69       86.74
    Record 10 |        404       13.26      100.00
--------------+-----------------------------------
        Total |      3,047      100.00

. list idnum latest if latest==0

      +----------------------+
      | idnum          latest |
      |----------------------|
 235. |  0235   Missing All 3 |
1131. |  1131   Missing All 3 |
1670. |  1670   Missing All 3 |
2320. |  2320   Missing All 3 |
2338. |  2338   Missing All 3 |
      |----------------------|
2940. |  2940   Missing All 3 |
      +----------------------+

.
. save "C:\NIDDK\MTOPS\Integrity\Analysis\Base_FU_EVENTS.dta", replace
file C:\NIDDK\MTOPS\Integrity\Analysis\Base_FU_EVENTS.dta saved

.
. * ############################
. *
. * For comparison, we also scan E forms so that we can re-check
. * our results and detect any discrepancies.
. *
. * ############################
.
. use "C:\NIDDK\mtops\SAS db\E Forms\E01\e012.dta", clear

. append using "C:\NIDDK\mtops\SAS db\E Forms\E01\e011.dta"

. drop if  ac4dec~=1
(780 observations deleted)

. tab1 ai4ss ai4grt ac4grt aivwk ac4dec

-> tabulation of ai4ss

init-sympto |
    m score |      Freq.     Percent        Cum.
------------+-----------------------------------
         12 |          1        0.37        0.37
         13 |          8        2.93        3.30
         14 |          7        2.56        5.86
         15 |          9        3.30        9.16
         16 |         15        5.49       14.65
         17 |         18        6.59       21.25
         18 |         15        5.49       26.74
         19 |         22        8.06       34.80
         20 |         17        6.23       41.03
         21 |         20        7.33       48.35
         22 |         21        7.69       56.04
         23 |         17        6.23       62.27
```

```
         24 |         16        5.86       68.13
         25 |         17        6.23       74.36
         26 |         15        5.49       79.85
         27 |          8        2.93       82.78
         28 |          4        1.47       84.25
         29 |          7        2.56       86.81
         30 |         12        4.40       91.21
         31 |         10        3.66       94.87
         32 |          4        1.47       96.34
         33 |          4        1.47       97.80
         34 |          3        1.10       98.90
         35 |          3        1.10      100.00
------------+-----------------------------------
      Total |        273      100.00

-> tabulation of ai4grt

    init->= |
 4+baseline |
          ? |      Freq.     Percent        Cum.
------------+-----------------------------------
          1 |        273      100.00      100.00
------------+-----------------------------------
      Total |        273      100.00

-> tabulation of ac4grt

    conf->= |
 4+baseline |
          ? |      Freq.     Percent        Cum.
------------+-----------------------------------
          1 |        273      100.00      100.00
------------+-----------------------------------
      Total |        273      100.00

-> tabulation of aivwk

       init |
 event-week |
   of visit |      Freq.     Percent        Cum.
------------+-----------------------------------
         11 |          1        0.37        0.37
         12 |          6        2.20        2.56
         13 |         11        4.03        6.59
         14 |          5        1.83        8.42
         15 |          2        0.73        9.16
         22 |          2        0.73        9.89
         23 |          1        0.37       10.26
         24 |          1        0.37       10.62
         25 |          3        1.10       11.72
         26 |         15        5.49       17.22
         27 |          2        0.73       17.95
         28 |          1        0.37       18.32
         37 |          1        0.37       18.68
         38 |         11        4.03       22.71
         39 |          6        2.20       24.91
         40 |          5        1.83       26.74
         41 |          1        0.37       27.11
         42 |          1        0.37       27.47
         43 |          1        0.37       27.84
         45 |          1        0.37       28.21
         51 |          9        3.30       31.50
         52 |          6        2.20       33.70
```

53	3	1.10	34.80
54	1	0.37	35.16
56	1	0.37	35.53
59	2	0.73	36.26
61	1	0.37	36.63
63	1	0.37	37.00
64	8	2.93	39.93
65	6	2.20	42.12
66	7	2.56	44.69
67	1	0.37	45.05
71	1	0.37	45.42
76	2	0.73	46.15
77	8	2.93	49.08
78	6	2.20	51.28
79	4	1.47	52.75
80	1	0.37	53.11
90	4	1.47	54.58
91	4	1.47	56.04
92	1	0.37	56.41
93	2	0.73	57.14
94	1	0.37	57.51
95	1	0.37	57.88
98	1	0.37	58.24
100	1	0.37	58.61
102	1	0.37	58.97
103	4	1.47	60.44
104	7	2.56	63.00
105	3	1.10	64.10
106	1	0.37	64.47
107	3	1.10	65.57
108	1	0.37	65.93
115	1	0.37	66.30
116	4	1.47	67.77
117	4	1.47	69.23
118	3	1.10	70.33
119	2	0.73	71.06
127	1	0.37	71.43
129	1	0.37	71.79
130	3	1.10	72.89
131	1	0.37	73.26
132	1	0.37	73.63
138	1	0.37	73.99
139	1	0.37	74.36
142	1	0.37	74.73
143	7	2.56	77.29
144	3	1.10	78.39
155	1	0.37	78.75
156	1	0.37	79.12
157	2	0.73	79.85
158	1	0.37	80.22
162	1	0.37	80.59
163	1	0.37	80.95
166	1	0.37	81.32
168	1	0.37	81.68
169	7	2.56	84.25
174	1	0.37	84.62
175	1	0.37	84.98
180	1	0.37	85.35
182	2	0.73	86.08
183	1	0.37	86.45
189	1	0.37	86.81
191	1	0.37	87.18
195	1	0.37	87.55

```
        196 |          4        1.47       89.01
        206 |          1        0.37       89.38
        208 |          4        1.47       90.84
        209 |          1        0.37       91.21
        210 |          2        0.73       91.94
        211 |          1        0.37       92.31
        220 |          2        0.73       93.04
        221 |          3        1.10       94.14
        223 |          1        0.37       94.51
        224 |          1        0.37       94.87
        234 |          1        0.37       95.24
        235 |          1        0.37       95.60
        236 |          2        0.73       96.34
        243 |          1        0.37       96.70
        248 |          1        0.37       97.07
        249 |          1        0.37       97.44
        250 |          1        0.37       97.80
        260 |          2        0.73       98.53
        261 |          1        0.37       98.90
        274 |          2        0.73       99.63
        359 |          1        0.37      100.00
------------+-----------------------------------
      Total |        273      100.00

-> tabulation of ac4dec

 conf-event |
 declared ? |      Freq.     Percent        Cum.
------------+-----------------------------------
          1 |        273      100.00      100.00
------------+-----------------------------------
      Total |        273      100.00

. tab ac4dec if  aivwk < 213

 conf-event |
 declared ? |      Freq.     Percent        Cum.
------------+-----------------------------------
          1 |        252      100.00      100.00
------------+-----------------------------------
      Total |        252      100.00

. sort idnum

. summarize ac4dec ac4wk

    Variable |       Obs        Mean    Std. Dev.       Min        Max
-------------+--------------------------------------------------------
      ac4dec |       273           1           0          1          1
       ac4wk |       273    100.3114    68.62276         14        363

. describe , short

Contains data from C:\NIDDK\mtops\SAS db\E Forms\E01\e012.dta
  obs:           273
 vars:            33
 size:        24,024 (99.9% of memory free)
Sorted by:  idnum
     Note:  dataset has changed since last saved

. save "C:\NIDDK\MTOPS\Integrity\Analysis\E_AUA.dta", replace
file C:\NIDDK\MTOPS\Integrity\Analysis\E_AUA.dta saved
```

```
.
. use "C:\niddk\mtops\SAS db\E Forms\E02\e022.dta", clear

. append using "C:\niddk\mtops\SAS db\E Forms\E02\e022.dta"

. tab1 ccvdec ccvdisc ccvgrt

-> tabulation of ccvdec

       conf |
event-event |
 declared ? |      Freq.     Percent        Cum.
------------+-----------------------------------
          2 |        116      100.00      100.00
------------+-----------------------------------
      Total |        116      100.00

-> tabulation of ccvdisc

       conf |
 event-date |
       meds |
    discont |      Freq.     Percent        Cum.
------------+-----------------------------------
  20 Aug 99 |          2      100.00      100.00
------------+-----------------------------------
      Total |          2      100.00

-> tabulation of ccvgrt

       conf |
   event->= |
      1.5 x |
   baseline |      Freq.     Percent        Cum.
------------+-----------------------------------
          1 |         44       44.90       44.90
          2 |         54       55.10      100.00
------------+-----------------------------------
      Total |         98      100.00

.
. ***
. *** NOTE ---> No creatinine rise events on E-02 forms <----
. ***
.
. use "C:\niddk\mtops\SAS db\E Forms\E03\e033.dta", clear

. append using "C:\niddk\mtops\SAS db\E Forms\E03\e032.dta"

. append using "C:\niddk\mtops\SAS db\E Forms\E03\e031.dta"

. tab1 nardec nutdec nindec

-> tabulation of nardec

retent-even |
 t declared |
          ? |      Freq.     Percent        Cum.
------------+-----------------------------------
          1 |         41       61.19       61.19
          2 |         26       38.81      100.00
------------+-----------------------------------
      Total |         67      100.00
```

```
-> tabulation of nutdec

infect-uros |
epsis event |
   declared |      Freq.     Percent        Cum.
------------+-----------------------------------
          1 |          5       71.43       71.43
          2 |          2       28.57      100.00
------------+-----------------------------------
      Total |          7      100.00

-> tabulation of nindec

incont-even |
 t declared |
          ? |      Freq.     Percent        Cum.
------------+-----------------------------------
          1 |         30       76.92       76.92
          2 |          9       23.08      100.00
------------+-----------------------------------
      Total |         39      100.00

. keep if nardec==1 | nutdec==1 | nindec==1
(40 observations deleted)

. sort idnum

. save "C:\NIDDK\MTOPS\Integrity\Analysis\E_UR.dta", replace
file C:\NIDDK\MTOPS\Integrity\Analysis\E_UR.dta saved

.
. * ############################
.
. use "C:\NIDDK\MTOPS\Integrity\Analysis\Base_FU_EVENTS.dta", clear

. sort idnum

. merge idnum using "C:\NIDDK\MTOPS\Integrity\Analysis\E_AUA.dta"

. sort idnum

. drop _merge

. merge idnum using "C:\NIDDK\MTOPS\Integrity\Analysis\E_UR.dta"

. sort idnum

. drop _merge

.
. generate AUAweek =  (AUA_date-rvstdt)/7
(2773 missing values generated)

. list AUA_date AUAweek aivwk if AUA==1 & _n<500

     +-----------------------------+
     |  AUA_date    AUAweek   aivwk |
     |-----------------------------|
  5. | 16 Oct 98         53      53 |
  6. | 01 Nov 00        169     169 |
 24. | 16 Jul 98   104.4286     104 |
 25. | 20 Apr 98   42.57143      43 |
 56. | 03 Jun 98   66.14286      66 |
```

```
     |-----------------------------|
  68. | 17 Dec 99   143.2857     143 |
  70. | 02 Nov 99   102.7143     103 |
  71. | 10 May 00   220.8571     221 |
  85. | 12 Nov 97         26      26 |
  92. | 11 Jun 99         80      80 |
     |-----------------------------|
  98. | 29 May 01        236     236 |
 110. | 03 May 99        104     104 |
 114. | 24 Feb 98   75.57143      76 |
 134. | 03 Apr 98   13.57143      13 |
 139. | 18 Feb 99         71      71 |
     |-----------------------------|
 145. | 20 Nov 97   78.14286      78 |
 148. | 07 Aug 98         90      90 |
 164. | 03 Dec 99   102.4286     102 |
 173. | 16 Oct 96        116     116 |
 180. | 29 Apr 98   64.71429      65 |
     |-----------------------------|
 189. | 14 Aug 95   63.57143      64 |
 199. | 26 Jul 00   209.8571     210 |
 203. | 01 Jun 99         77      77 |
 214. | 07 Dec 00        169     169 |
 237. | 16 Apr 99   65.14286      65 |
     |-----------------------------|
 255. | 26 Nov 01        274     274 |
 276. | 07 Feb 01        221     221 |
 278. | 14 Mar 00        116     116 |
 279. | 12 Nov 97   77.28571      78 |
 280. | 19 Mar 98   51.85714      52 |
     |-----------------------------|
 284. | 23 Sep 98   223.7143     224 |
 319. | 29 Nov 00   233.8571     234 |
 342. | 29 May 97         65      65 |
 343. | 17 Mar 97         38      38 |
 350. | 30 Oct 97   13.14286      13 |
     |-----------------------------|
 364. | 18 Jun 99   79.14286      79 |
 373. | 07 Dec 98   65.42857      66 |
 383. | 24 Apr 98   38.14286      38 |
 394. | 07 Aug 96   12.85714      13 |
 399. | 18 Aug 01   236.4286     236 |
     |-----------------------------|
 416. | 27 Aug 97   53.28571      53 |
 437. | 09 Dec 97   50.71429      51 |
 445. | 31 Oct 96         13      13 |
 447. | 25 May 99        117     117 |
 453. | 26 Mar 98   38.85714      39 |
     |-----------------------------|
 464. | 15 Oct 01        221     221 |
 477. | 26 May 99   131.7143     132 |
 482. | 31 Mar 99   98.28571      98 |
 488. | 08 Jan 97   14.14286      14 |
     +-----------------------------+

. generate AUAweek2 =  round(AUAweek)
(2773 missing values generated)

. list AUA_date AUAweek2 aivwk if AUA==1 & _n <100

     +-----------------------------+
     |  AUA_date   AUAweek2   aivwk |
     |-----------------------------|
```

```
   5. | 16 Oct 98         53      53 |
   6. | 01 Nov 00        169     169 |
  24. | 16 Jul 98        104     104 |
  25. | 20 Apr 98         43      43 |
  56. | 03 Jun 98         66      66 |
      |------------------------------|
  68. | 17 Dec 99        143     143 |
  70. | 02 Nov 99        103     103 |
  71. | 10 May 00        221     221 |
  85. | 12 Nov 97         26      26 |
  92. | 11 Jun 99         80      80 |
      |------------------------------|
  98. | 29 May 01        236     236 |
      +------------------------------+

. tab AUA ac4dec

           | conf-event
           | declared ?
       AUA |         1 |     Total
-----------+-----------+----------
         1 |       273 |       273
-----------+-----------+----------
     Total |       273 |       273


. correlate aivwk AUAweek2
(obs=273)

             |    aivwk AUAweek2
-------------+------------------
       aivwk |   1.0000
    AUAweek2 |   1.0000   1.0000


. replace AUAweek2 = 212 if AUAweek2<213
(253 real changes made)

. replace aivwk =212 if aivwk<213
(252 real changes made)

. tab AUAweek2 drug if AUA==1 & AUAweek2==212

           |                treatment group
  AUAweek2 |   Placebo  Doxazosin  Finasteri  Combinati |     Total
-----------+--------------------------------------------+----------
       212 |        97         55         65         36 |       253
-----------+--------------------------------------------+----------
     Total |        97         55         65         36 |       253


. tab aivwk drug if  ac4dec==1 & aivwk==212

      init |
event-week |                treatment group
  of visit |   Placebo  Doxazosin  Finasteri  Combinati |     Total
-----------+--------------------------------------------+----------
       212 |        96         55         65         36 |       252
-----------+--------------------------------------------+----------
     Total |        96         55         65         36 |       252


.
```

```
. list idnum AUA ac4dec if AUA==1 & ac4dec~ = 1

      +----------------------+
      | idnum   AUA   ac4dec |
      |----------------------|
2590. |  2590     1        . |
      +----------------------+

. generate URweek =  (UR_date-rvstdt)/7
(2970 missing values generated)

. generate URweek2 =  round(URweek)
(2970 missing values generated)

. list UR_date URweek URweek2 nviwk if URevent==1 & _n<500

      +-----------------------------------------+
      |   UR_date     URweek   URweek2   nviwk |
      |-----------------------------------------|
   2. | 16 Dec 98   103.2857       103     103 |
  53. | 02 Feb 98   21.71428        22      22 |
 166. | 26 Nov 99   189.2857       189     195 |
 171. | 01 Nov 97   58.71429        59      78 |
 206. | 20 Jun 00   215.1429       215     215 |
      |-----------------------------------------|
 267. | 06 Feb 00   167.2857       167     168 |
 296. | 03 Aug 98   222.5714       223     261 |
 339. | 13 Aug 96         17        17      17 |
 369. | 09 May 95         60        60      60 |
 400. | 24 Aug 01   260.5714       261     260 |
      |-----------------------------------------|
 425. | 05 Apr 99   157.7143       158     158 |
 428. | 16 Mar 00        176       176     200 |
 441. | 25 Dec 98   63.14286        63      77 |
 485. | 06 Nov 00   158.5714       159     159 |
 490. | 25 Oct 00   221.1429       221     217 |
      +-----------------------------------------+

. correlate nviwk URweek2
(obs=76)

             |    nviwk  URweek2
-------------+------------------
       nviwk |   1.0000
     URweek2 |   0.9700   1.0000


. replace URweek2 = 212 if URweek2<213
(61 real changes made)

. replace nviwk =212 if nviwk<213
(58 real changes made)

. sort UR_Type

. by UR_Type: tab URweek2 drug if URevent==1 & URweek2==212

-------------------------------------------------------------------------------
-> UR_Type = None
no observations

-------------------------------------------------------------------------------
-> UR_Type = Retention
```

```
           |                treatment group
   URweek2 |   Placebo  Doxazosin  Finasteri  Combinati |     Total
-----------+--------------------------------------------+----------
       212 |        18          9          6          3 |        36
-----------+--------------------------------------------+----------
     Total |        18          9          6          3 |        36
```

```
-> UR_Type = U Infection
```

```
           |         treatment group
   URweek2 |   Placebo  Doxazosin  Combinati |     Total
-----------+---------------------------------+----------
       212 |         1          2          1 |         4
-----------+---------------------------------+----------
     Total |         1          2          1 |         4
```

```
-> UR_Type = Incontinence
```

```
           |                treatment group
   URweek2 |   Placebo  Doxazosin  Finasteri  Combinati |     Total
-----------+--------------------------------------------+----------
       212 |         6          7          7          1 |        21
-----------+--------------------------------------------+----------
     Total |         6          7          7          1 |        21
```

```
. tab nviwk drug if nardec==1 & nviwk==212
```

```
   week of |
   initial |
     event |                treatment group
     visit |   Placebo  Doxazosin  Finasteri  Combinati |     Total
-----------+--------------------------------------------+----------
       212 |        17          9          6          3 |        35
-----------+--------------------------------------------+----------
     Total |        17          9          6          3 |        35
```

```
. tab nviwk drug  if nutdec==1 & nviwk==212
```

```
   week of |
   initial |
     event |    treatment group
     visit |   Placebo  Doxazosin |     Total
-----------+----------------------+----------
       212 |         1          2 |         3
-----------+----------------------+----------
     Total |         1          2 |         3
```

```
. tab nviwk drug if nindec==1 & nviwk==212
```

```
   week of |
   initial |
     event |                treatment group
     visit |   Placebo  Doxazosin  Finasteri  Combinati |     Total
-----------+--------------------------------------------+----------
       212 |         6          6          7          1 |        20
```

```
-----------+--------------------------------------------+----------
     Total |         6          6          7          1 |        20
```

```
. list idnum URevent nardec nutdec nindec if URevent==1 & (nardec~=1 & nutdec~=1 & nindec~=1)

      +-----------------------------------------+
      | idnum   URevent   nardec   nutdec   nindec |
      |-----------------------------------------|
3018. |  2968         1        .        .        . |
      +-----------------------------------------+
```

```
.
. generate XINVweek =  (XInvasive_date - rvstdt)/7
(2795 missing values generated)

. generate XINVweek2 = round(XINVweek)
(2795 missing values generated)

. list XInvasive_date XINVweek XINVweek2 rvstdt if  XInvasive_type>0 & _n<500

      +-----------------------------------------------+
      | XInvas~te   XINVweek   XINVwe~2      rvstdt |
      |-----------------------------------------------|
   2. | 01 Oct 97   69.28571         69   03 Jun 96 |
   9. | 25 Feb 99   117.2857        117   26 Nov 96 |
  59. | 27 Mar 00   122.4286        122   21 Nov 97 |
  85. | 01 Mar 98   99.85714        100   01 Apr 96 |
  87. | 01 May 98   96.28571         96   26 Jun 96 |
      |-----------------------------------------------|
  88. | 07 Jan 99   83.85714         84   30 May 97 |
  91. | 30 May 01   192.8571        193   18 Sep 97 |
 101. | 27 Aug 99   178.2857        178   27 Mar 96 |
 105. | 28 Mar 95   30.57143         31   26 Aug 94 |
 109. | 16 Apr 01   233.5714        234   24 Oct 96 |
      |-----------------------------------------------|
 122. | 16 Jul 97         79         79   10 Jan 96 |
 123. | 24 Feb 00        173        173   31 Oct 96 |
 182. | 02 Sep 99        140        140   26 Dec 96 |
 183. | 16 Jul 01   281.7143        282   21 Feb 96 |
 189. | 16 Feb 95   27.14286         27   10 Aug 94 |
      |-----------------------------------------------|
 209. | 22 Feb 99         66         66   17 Nov 97 |
 216. | 06 Nov 98   62.57143         63   25 Aug 97 |
 221. | 01 Jun 97   71.85714         72   15 Jan 96 |
 231. | 22 Jul 99   140.1429        140   13 Nov 96 |
 242. | 07 Sep 00   211.4286        211   19 Aug 96 |
      |-----------------------------------------------|
 254. | 03 Sep 97   62.85714         63   20 Jun 96 |
 264. | 22 Sep 98   85.57143         86   31 Jan 97 |
 296. | 19 Jun 98   59.57143         60   28 Apr 97 |
 323. | 26 Feb 01   218.4286        218   20 Dec 96 |
 352. | 23 May 01   191.8571        192   18 Sep 97 |
      |-----------------------------------------------|
 357. | 30 Nov 94   14.14286         14   23 Aug 94 |
 393. | 11 May 00        172        172   23 Jan 97 |
 407. | 08 Mar 01   194.1429        194   18 Jun 97 |
 409. | 22 Oct 98   94.42857         94   30 Dec 96 |
 428. | 11 Apr 00   163.8571        164   19 Feb 97 |
      |-----------------------------------------------|
 449. | 28 Feb 00   144.7143        145   21 May 97 |
 472. | 11 Sep 00   159.7143        160   20 Aug 97 |
```

```
 486. | 14 Jul 98        105        105   09 Jul 96 |
 491. | 28 Jan 99   138.8571        139   31 May 96 |
      +----------------------------------------------+

. replace XINVweek2 = 212 if XINVweek2 < 213
(206 real changes made)

.
. *** Analysis using ALL invasive therapies ***
.
. tab XInvasive_type drug if XINVweek2==212 & XInvasive_type>0

   xover-specify |               treatment group
invasive therapy |   Placebo  Doxazosin  Finasteri  Combinati |     Total
-----------------+--------------------------------------------+----------
            TURP |        29         17          9          8 |        63
            TUIP |         1          1          0          1 |         3
Radical Prstctmy |        14         14          7         23 |        58
   Open Prstctmy |         1          2          2          0 |         5
            TUNA |         3          0          1          0 |         4
       Microwave |         3          3          1          0 |         7
           Laser |         0          0          1          1 |         2
           Other |        13         18         15         20 |        66
-----------------+--------------------------------------------+----------
           Total |        64         55         36         53 |       208


. tab wctitx

          xover-other invasive therapy |      Freq.     Percent        Cum.
---------------------------------------+-----------------------------------
                                   BCG |          2        2.56        2.56
                 BLADDER FULGURATION |          1        1.28        3.85
               EXTERNAL BEAM RADIATION |         32       41.03       44.87
EXTERNAL BEAM RADIATION & RADIATION SEE |          1        1.28       46.15
HIGH INTENSITY FOCUSED ULTRASOUND THERM |          1        1.28       47.44
                          ORCHIECTOMY |          1        1.28       48.72
                     RADIATION SEEDS |         24       30.77       79.49
      RADICAL CYSTECTOMY/PROSTATECTOMY |          1        1.28       80.77
              RADIOFREQUENCY TREATMENT |          1        1.28       82.05
                                TURBT |         10       12.82       94.87
                           TURP/TURBT |          3        3.85       98.72
               UNKNOWN THERAPY FOR BPH |          1        1.28      100.00
---------------------------------------+-----------------------------------
                                 Total |         78      100.00

.
. *** Analysis dropping Radical Prostatectomy and "Other" therapies ***
.
. replace XInvasive_type=0 if XInvasive_type==3
(70 real changes made)

. replace XInvasive_type=0 if XInvasive_type==9
(78 real changes made)

. tab XINVweek2 drug if XINVweek2==212 & XInvasive_type>0

           |               treatment group
 XINVweek2 |   Placebo  Doxazosin  Finasteri  Combinati |     Total
-----------+--------------------------------------------+----------
       212 |        37         23         14         10 |        84
-----------+--------------------------------------------+----------
     Total |        37         23         14         10 |        84
```

```
. tab XInvasive_type drug if XINVweek2==212 & XInvasive_type>0

   xover-specify |               treatment group
invasive therapy |   Placebo  Doxazosin  Finasteri  Combinati |     Total
-----------------+--------------------------------------------+----------
            TURP |        29         17          9          8 |        63
            TUIP |         1          1          0          1 |         3
   Open Prstctmy |         1          2          2          0 |         5
            TUNA |         3          0          1          0 |         4
       Microwave |         3          3          1          0 |         7
           Laser |         0          0          1          1 |         2
-----------------+--------------------------------------------+----------
           Total |        37         23         14         10 |        84


. tab wctitx drug if XINVweek2==212

 xover-other invasive |               treatment group
              therapy |   Placebo  Doxazosin  Finasteri  Combinati |     Total
----------------------+--------------------------------------------+----------
                  BCG |         0          0          1          1 |         2
  BLADDER FULGURATION |         0          0          1          0 |         1
EXTERNAL BEAM RADIATI |         3          8          6          7 |        24
          ORCHIECTOMY |         0          0          1          0 |         1
      RADIATION SEEDS |         8          5          5          6 |        24
RADICAL CYSTECTOMY/PR |         0          0          0          1 |         1
RADIOFREQUENCY TREATM |         0          1          0          0 |         1
                TURBT |         2          2          1          3 |         8
            TURP/TURBT |         0          2          0          1 |         3
UNKNOWN THERAPY FOR B |         0          0          0          1 |         1
----------------------+--------------------------------------------+----------
                Total |        13         18         15         20 |        66


.
. *** FINAL ANALYSES get frequecy distribution for time in study and
. *** generate results ONLY for subjects with 212 or more
. *** weeks of Follow UP
.
. tab END_collapsed

END_collaps |
         ed |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |         18        0.59        0.59
       1-99 |        204        6.70        7.29
    100-199 |        424       13.92       21.20
    225-299 |      2,287       75.06       96.26
       300+ |        114        3.74      100.00
------------+-----------------------------------
      Total |      3,047      100.00

. drop if END<212
(1276 observations deleted)

. tab AUAweek2 drug if AUA==1 & AUAweek2==212

           |               treatment group
  AUAweek2 |   Placebo  Doxazosin  Finasteri  Combinati |     Total
-----------+--------------------------------------------+----------
       212 |        55         34         34         24 |       147
```

```
-----------+--------------------------------------------+----------
     Total |        55         34         34         24 |       147
```

```
. tab XINVweek2 drug if XINVweek2==212 & XInvasive_type>0
```

```
           |                treatment group
 XINVweek2 |   Placebo  Doxazosin  Finasteri  Combinati |     Total
-----------+--------------------------------------------+----------
       212 |        23         14          8          7 |        52
-----------+--------------------------------------------+----------
     Total |        23         14          8          7 |        52
```

```
. by UR_Type: tab URweek2 drug if XINVweek2==212 & URevent==1 & UR_Type>0
```

```
-------------------------------------------------------------------------------
-> UR_Type = None
no observations
```

```
-------------------------------------------------------------------------------
-> UR_Type = Retention
```

```
           |                treatment group
   URweek2 |   Placebo  Doxazosin  Finasteri  Combinati |     Total
-----------+--------------------------------------------+----------
       212 |         7          4          3          2 |        16
-----------+--------------------------------------------+----------
     Total |         7          4          3          2 |        16
```

```
-------------------------------------------------------------------------------
-> UR_Type = U Infection
```

```
           | treatment
           |   group
   URweek2 |   Placebo |     Total
-----------+-----------+----------
       212 |         1 |         1
-----------+-----------+----------
     Total |         1 |         1
```

```
-------------------------------------------------------------------------------
-> UR_Type = Incontinence
```

```
           |    treatment group
   URweek2 |   Placebo  Doxazosin |     Total
-----------+----------------------+----------
       212 |         1          1 |         2
-----------+----------------------+----------
     Total |         1          1 |         2
```

```
end of do-file

. log close
      log:  C:\NIDDK\MTOPS\Integrity\Analysis\FU_Analyses.log
  log type:  text
 closed on:   5 Jul 2006, 08:25:07
```