Dataset Integrity Check for the ETOMUS Data Files

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Contents

1 Standard Disclaimer

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

2 Study Background

E-TOMUS is an observational study of women who have completed participation in theTrial Of Mid-Urethral Slings (TOMUS), a randomized trial comparing retropubic and transobturator midurethral sling procedures in women undergoing surgery for stress urinary incontinence (SUI). The TOMUS study follows participants for 2-years after surgery. Since 2-years is too short to evaluate long-term sequelae of the procedures, the goal of E-TOMUS is to follow participants for 5 additional years to compare the long-term continence rates, complication rates and overall pelvic floor outcomes of the two procedures.

3 Archived Datasets

All SAS data files, as provided by the Data Coordinating Center (DCC), are located in the “” folder in the data package. For this replication, variables were taken from those datasets only.

4 Statistical Methods

Analyses were performed to duplicate results for the data published by Kenton, Kimberly, et al. in The Journal of urology, 2015. To verify the integrity of the datasets, a table from the paper was checked (Table B)

5 Results

Table 1 in the publication [1], Table 1: Baseline Characteristics of Women Enrolled and Not Enrolled in Observational Cohort Study. Table A lists the variables that were used in the replication and Table B compares the results calculated from the archived data file to the results published in Table 1. The results of the replication are incomplete.

Note that there was an error regarding the Menopausal Status field in Table 1 of the publication. The authors of the publication were notified of this error and plan to issue a correction in the future. Please see the differences noted in Table B below for more details.

6 Conclusions

The NIDDK repository are not yet confident that the ETOMUS data files to be distributed are a copy of the manuscript data with only inconsequential discrepancies.

7 References

[1] Kenton, Kimberly, et al. "5-Year longitudinal followup after retropubic and transobturator mid urethral slings." The Journal of urology 193.1 (2015): 203-210.

Table A: Variables used to replicate Table 1: Baseline Characteristics of Women Enrolled and Not Enrolled in Observational Cohort Study.

Characteristic	Variable(s)
Age (years): Mean±SD	Finlstat.AGE
Racial and Ethnicity Group N (%)	TOMUS baseline dataset, hispanic
Married/Living as Married N (%)	TOMUS baseline dataset, marstat
Education n (%)	TOMUS baseline dataset, educ
BMI: Mean±SD	TOMUS baseline dataset, bmi
Vaginal Nulliparous N (%)	TOMUS baseline dataset, v_del (if v_del = 0)
Prior Incontinence Surgery N (%)	TOMUS baseline dataset, uisurg
Menopausal Status N (%)	TOMUS baseline dataset, menop and any_hrt
Concomitant Surgery N (%)	Finlstat.concomsx
Leaks/day:	TOMUS baseline dataset, ave_acc
Pad test: Median (10th, 90th %)	TOMUS baseline dataset, diffwt
Pelvic Organ Prolapse Quantification Stage N (%)	TOMUS baseline dataset, stagecat
Urinary Distress Inventory Mean±SD	etomus_longitudinal.UDI_TOT
Incontinence Impact Questionnaire Mean±SD	etomus_longitudinal.IIQ_TOT
MESA Stress Index Mean±SD	TOMUS baseline dataset, stress_index1
MESA Urge Index Mean±SD	TOMUS baseline dataset, urge_index1

Table B: Comparison of values computed in integrity check to reference article Table 1 values

Characteristics	Enrolled Manuscript (N=404)	Enrolled DSIC (N=404)	Enrolled DIFF (N=0)
Demographic Characteristics			
Age (years): Mean±SD	53.7 (± 10.48)	53.7 (± 10.48)	0,0
Racial and Ethnicity Group N (%)			
Hispanic	42 (10.4%)	42 (10.4%)	0,0
Non-Hispanic White	328 (81.2%)	328 (81.2%)	0,0
Non-Hispanic Black	12 (3.0%)	12 (3.0%)	0,0
Non-Hispanic Other	22 (5.4%)	22 (5.4%)	0,0
Married/Living as Married N (%)	285 (70.5%)	285 (70.5%)	0,0
Education n (%)			
High School or Less	120 (29.7%)	120 (29.7%)	0,0
Post High School	143 (35.4%)	143 (35.4%)	0,0
Bachelors or more	141 (34.9%)	141 (34.9%)	0,0
Risk Factors for Urinary Incontinence			
BMI: Mean±SD	30.3 (± 6.59)	30.3 (± 6.59)	0,0
Vaginal Nulliparous N (%)	46 (11.4%)	46 (11.4%)	0,0
Prior Incontinence Surgery N (%)	54 (13.4%)	54 (13.4%)	0,0
Menopausal Status N (%)			
Premenopausal	154 (38.1%)	115 (28.5%)	-39, -9.6
Postmenopausal not using HRT	135 (33.4%)	154 (38.1%)	19, 4.7
Postmenopausal using HRT	115 (28.5%)	135 (33.4%)	20, 4.9
Concomitant Surgery N (%)	105 (26.0%)	105 (26.0%)	0,0
Leaks/day: Median (10th, 90th %)	2.7 (0.67, 6.67)	2.7 (0.67, 6.67)	0,0
Pad test: Median (10th, 90th %)	12.1 (3.39, 92.85)	12.1 (3.39, 92.85)	0,0
Pelvic Organ Prolapse Quantification Stage N (%)			
Stage 0/I	178 (44.1%)	178 (44.1%)	0,0
Stage II	195 (48.3%)	195 (48.3%)	0,0
Stage III/IV	31 (7.7%)	31 (7.7%)	0,0
Quality of Life			
Urinary Distress Inventory Mean±SD	134.8 (± 44.11)	134.8 (± 44.11)	0,0
Incontinence Impact Questionnaire Mean±SD	147.3 (± 96.02)	147.3 (± 96.02)	0,0
MESA Stress Index Mean±SD	71.7 (± 16.84)	71.7 (± 16.84)	0,0
MESA Urge Index Mean±SD	35.5 (± 21.97)	35.5 (± 21.97)	0,0

Characteristics	Not Enrolled Manuscript (N=193)	Not Enrolled DSIC (N=193)	Not Enrolled DIFF (N=0)
Demographic Characteristics			
Age (years): Mean±SD	51.2 (± 11.83)	51.2 (± 11.83)	0,0
Racial and Ethnicity Group N (%)			
Hispanic	29 (15.0%)	29 (15.0%)	0,0
Non-Hispanic White	145 (75.1%)	145 (75.1%)	0,0
Non-Hispanic Black	5 (2.6%)	5 (2.6%)	0,0
Non-Hispanic Other	14 (7.3%)	14 (7.3%)	0,0
Married/Living as Married N (%)	127 (65.8%)	127 (65.8%)	0,0
Education n (%)			
High School or Less	64 (33.2%)	64 (33.2%)	0,0
Post High School	74 (38.3%)	74 (38.3%)	0,0
Bachelors or more	55 (28.5%)	55 (28.5%)	0,0
Risk Factors for Urinary Incontinence			
BMI: Mean±SD	30.3 (± 7.03)	30.3 (± 7.03)	0,0
Vaginal Nulliparous N (%)	24 (12.4%)	24 (12.4%)	0,0
Prior Incontinence Surgery N (%)	25 (13.1%)	25 (13.1%)	0,0
Menopausal Status N (%)			
Premenopausal	90 (47.1%)	65 (34.0%)	-25 ,-13.1
Postmenopausal not using HRT	36 (18.8%)	90 (47.1%)	54, 28.3
Postmenopausal using HRT	65 (34.0%)	36 (18.8%)	-29, -15.2
Concomitant Surgery N (%)	46 (23.8%)	46 (23.8%)	0,0
Leaks/day: Median (10th, 90th %)	2.7 (0.67, 6.67)	2.7 (0.67, 6.67)	0,0
Pad test: Median (10th, 90th %)	13.4 (4.13, 78.64)	13.4 (4.13, 78.64)	0,0
Pelvic Organ Prolapse Quantification Stage N (%)			
Stage 0/I	89 (46.1%)	89 (46.1%)	0,0
Stage II	87 (45.1%)	87 (45.1%)	0,0
Stage III/IV	17 (8.8%)	17 (8.8%)	0,0
Quality of Life			
Urinary Distress Inventory Mean±SD	134.0 (± 48.36)	134.0 (± 48.36)	0,0
Incontinence Impact Questionnaire Mean±SD	160.3 (± 99.77)	160.3 (± 99.77)	0,0
MESA Stress Index Mean±SD	71.3 (± 17.51)	71.3 (± 17.51)	0,0
MESA Urge Index Mean±SD	33.2 (± 22.22)	33.2 (± 22.22)	0.0

Table C: Variables used to replicate Table 2: Overall Treatment Success by Sling Treatment Group at 5 year Visit (n=583)

Characteristic	Variable(s)
Sling group – retropubic vs transobturator	Finlstat.retropubic
Complete cases	Finlstat.etm_status_60 = 1,3
Success/Fail counts in Complete Cases	Finlstat. etmfail_01_60
Sling group numbers in Sensitivity Analyses	Finlstat.retropubic
Success or fail counts in Sensitivity Analyses	Finlstat.etm_status_60 etm_status_60 = 1 Success, etm_status_60 = 3 Fail Code the lost (etm_status_60 = 2) as either success or failure depending on the assumptions.

Table D: Comparison of values computed for integrity check of reference article Table 2 values

Characteristic	Table 2 Values		DSIC		Difference
	Retropubic	Transobturator	Retropubic	Transobturator	
Complete Cases	189	217	189	217	0
	72 (38.1%)	75 (34.6%)	72 (38.1%)	75 (34.6%)	0
Sensitivity Analyses					
n	291	292	291	292	0
All treatments: Lost=success	174 (59.8%)	150 (51.4%)	174 (59.8%)	150 (51.4%)	0
All treatments: Lost=failure	72 (24.7%)	75 (25.7%)	72 (24.7%)	75 (25.7%)	0
Retropubic: lost=success; Transobturator: lost=failure	174 (59.8%)	75 (25.7%)	174 (59.8%)	75 (25.7%)	0
Retropubic: lost=failure; Transobturator: lost=success	72 (24.7%)	150 (51.4%)	72 (24.7%)	150 (51.4%)	0

Attachment A: SAS Code

```
%let flnm = %sysfunc(getoption(sysin));
title "Program saved as: &FLNM.";
title2 "Check ETOMUS input files for DSIC";

/*************************************************************************************************************************************
Programmer: Michael Spriggs
Date: 17 February 2015

Function/Notes: Check ETOMUS input files for DSIC

March 11, 2015:  Patty Griffin - add TOMUS dataset fields that were used for ETOMUS
*************************************************************************************************************************************/
*  Input file  *;
****************;
libname inlib "/nobackup_btp/niddk/ETOMUS/private_orig_data/ETOMUS/Datasets";
libname tomus "/prj/niddk/public_orig_data/TOMUS_V1/3_TOMUS_Data/Data";

options nofmterr;

*************;
*  Formats  *;
*************;
proc format;
  value partfmt
    1 = "1: Yes"
    2 = "2: No, patient refused"
    3 = "3: No, unable to contact patient"
    4 = "4: No, patient refused any futur"
    5 = "5: No, other reason"
    ;
  value part2fmt
    0 = "0: No"
    1 = "1: Yes"
    ;

  value race_ethnicity
  1 = 'Hispanic'
  2 = 'Non-hispanic White'
  3 = 'Non-hispanic Black'
  4 = 'Non-hispanic Other'
  ;

  value education
  1, 2 = 'HS or less'
  3 = 'Post HS'
  4,5 = 'Bachelors or more'
  ;

************;
*  Macro  *;
************;
%macro poplimit (dsn);
data &DSN.;
```

```
  set &DSN.;
  by AID;
  if visit="BASE" then vc=0;
  else if visit="TF2W" then vc=1;
  else if visit="TF6W" then vc=2;
  else if visit="TF06" then vc=3;
  else if visit="TF12" then vc=4;
  else if visit="TF24" then vc=5;
  else if visit="ET36" then vc=6;
  else if visit="ET48" then vc=7;
  else if visit="ET60" then vc=8;
  else if visit="ET72" then vc=9;
  else if visit="ET84" then vc=10;

proc sort data=&dsn;
  by AID vc;

data &DSN.;
  set &dsn.;
  by AID;
  if first.AID then output;

run;
%mend;

%macro checkpii (wfn,dsn);
data &DSN.;
  set inlib.&WFN.;
run;

proc contents data = &DSN.;
  title4 "Contents of &WFN.";
run;
/*
proc freq data = &DSN.;
  title4 "Frequency of all variables on &WFN.";
run;
*/
%mend;

%global caser;
%let caser=part2;

*** Macro ***;
%macro freqdata1(order=, invar=, level=);

data data0 data1;
  set _null_;

  proc freq data=table1 noprint;
       tables &invar*&caser/out=data0 outpct;
       format _all_;
       run;

data data1;
  set data0;
```

```
  length LEVEL $100;
  LEVEL=strip(&invar);

  data data1(keep=LEVEL &caser name CHARALL ORDERER);
    set data1;
    length name $100 CHARALL $100;
    name=upcase("&invar");
    PCT_DISP=round(PCT_COL,.1);
    CHARALL=compress(put(COUNT,8.))||" ("||compress(put(PCT_DISP,8.1))||")";
    ORDERER=&order;
    if level in &level then output data1;

data accumfreq1;
  set accumfreq1 data1;

%mend freqdata1;

%macro meandata1(order=, invar=, meanroundvar=, stddevroundvar=);
proc means data=table1 mean stddev noprint;
        var &invar;
        class &caser;
        output out=data1 mean=mean stddev=stddev;
        run;

data data1(drop=_TYPE_ _FREQ_ mean stddev mdig sdig);
  set data1;
  length name CHARALL $100;
  name=upcase("&invar");
  mdig=(10**(-1*&meanroundvar));
  sdig=(10**(-1*&stddevroundvar));
  mean=round(mean,mdig);
  stddev=round(stddev,sdig);
  CHARALL=compress(put(mean,8.&meanroundvar))||" ± "||compress(put(stddev,8.&stddevroundvar));
  ORDERER=&order;

data accummean1;
  set accummean1 data1;

%mend meandata1;

%macro mediandata1(order=, invar=, roundvar=, digit=);
proc means data=table1 median p10 p90 min max noprint;
        var &invar;
        class &caser;
        output out=data1 median=median p10=p10 p90=p90 min=min max=max;
        run;

data data1(drop=_TYPE_ _FREQ_ median p10 p90 min max);
  set data1;
  length name CHARALL $100;
  name=upcase("&invar");
  median=round(median,&roundvar);
  min=round(min,&roundvar);
  max=round(max,&roundvar);
  ORDERER=&order;
  CHARALL=compress(put(median,8.&digit));
```

```
  output;
  ORDERER=ORDERER+.01;
  *CHARALL=compress(put(min,8.&digit)||"-"||put(max,8.&digit));
  CHARALL=compress(put(p10,8.&digit)||","||put(p90,8.&digit));
  output;

data accummedian1;
  set accummedian1 data1;

%mend mediandata1;

%macro rangedata1(order=, invar=, roundvar=, digit=);
proc means data=table1 median p25 p75 min max noprint;
       var &invar;
       class &caser;
       output out=data1 min=min max=max;
       run;

data data1(drop=_TYPE_ _FREQ_ min max);
  set data1;
  length name CHARALL $100;
  name=upcase("&invar");
  min=round(min,&roundvar);
  max=round(max,&roundvar);
  ORDERER=&order;
  CHARALL=compress(put(min,8.&digit)||"-"||put(max,8.&digit));
  output;

data accummedian1;
  set accummedian1 data1;

%mend rangedata1;
%macro inertdata1(order=);

data inert1;
  length orderer &caser 8.;
  orderer=&order.;
  &caser=-1;
  output;
  orderer=&order.;
  &caser=0;
  output;
  orderer=&order.;
  &caser=1;
  output;

data accuminert1;
  set accuminert1 inert1;

%mend inertdata1;

%macro datachunk();

%meandata1(order=1, invar=AGE, meanroundvar=1, stddevroundvar=2);
*%meandata1(order=2, invar=BMI, meanroundvar=1, stddevroundvar=2);
*%freqdata1(order=3, invar=PRIOR_TREAT, level=("1"));
```

```
%freqdata1(order=4, invar=POPQ_STAGE, level=("Stage 0/I"));
%freqdata1(order=5, invar=POPQ_STAGE, level=("Stage II"));
%freqdata1(order=6, invar=POPQ_STAGE, level=("Stage III/IV"));
%freqdata1(order=7, invar=concomsx, level=("1"));
%meandata1(order=8, invar=UDI_TOT, meanroundvar=1, stddevroundvar=2);
%meandata1(order=9, invar=IIQ_TOT, meanroundvar=1, stddevroundvar=2);
%freqdata1(order=10, invar=RACE_ETHNICITY, level=("Hispanic"));
%freqdata1(order=11, invar=RACE_ETHNICITY, level=("Non-hispanic White"));
%freqdata1(order=12, invar=RACE_ETHNICITY, level=("Non-hispanic Black"));
%freqdata1(order=13, invar=RACE_ETHNICITY, level=("Non-hispanic Other"));
%freqdata1(order=14, invar=MARRIED, level=("1"));
%freqdata1(order=15, invar=EDUCATION, level=("HS or less"));
%freqdata1(order=16, invar=EDUCATION, level=("Post HS"));
%freqdata1(order=17, invar=EDUCATION, level=("Bachelors or more"));
%freqdata1(order=18, invar=VAGINAL_NULLIPAROUS, level=("1"));
%meandata1(order=19, invar=BASELINE_BMI, meanroundvar=1, stddevroundvar=2);
%freqdata1(order=20, invar=PRIOR_UI_SURGERY, level=("1"));
%freqdata1(order=21, invar=MENOPAUSE, level=("Premenopausal"));
%freqdata1(order=22, invar=MENOPAUSE, level=("Postmenopausal not using HRT"));
%freqdata1(order=23, invar=MENOPAUSE, level=("Postmenopausal using HRT"));
%mediandata1(order=24, invar=AVE_ACC, roundvar=.1, digit=2);
%mediandata1(order=25, invar=PAD_TEST, roundvar=.1, digit=2);
%meandata1(order=26, invar=stress_index1, meanroundvar=1, stddevroundvar=2);
%meandata1(order=27, invar=urge_index1, meanroundvar=1, stddevroundvar=2);

%mend datachunk;

*****************************************************;
*  Create the report for all of the datasets in inlib  *;
*****************************************************;
%checkpii (wfn=etomus_longitudinal,dsn=ethlon);
%checkpii (wfn=f370,dsn=f370);
%checkpii (wfn=f371,dsn=f371);
%checkpii (wfn=f372,dsn=f372);
%checkpii (wfn=f373,dsn=f373);
%checkpii (wfn=f374,dsn=f374);
%checkpii (wfn=f376,dsn=f376);
%checkpii (wfn=f377,dsn=f377);
%checkpii (wfn=f378,dsn=f378);
%checkpii (wfn=finlstat,dsn=finlstat);

data finlstat;
  set finlstat;
  length VISIT $4;
  VISIT=LAST_VISIT;
  format _all_;

data f372;
  set f372;
  format _all_;

data f374;
  set f374;
  format _all_;

proc sort data=finlstat;
```

```
  by AID VISIT;

proc freq data=finlstat;
  tables LAST_VISIT/missing list;
  title4 'finlstat visit information';

proc freq data=f372;
  tables VISIT;
  title4 'f372 visit information';

proc freq data=f374;
  tables VISIT;
  title4 'f374 visit information';

proc freq data=ethlon;
  tables VISIT;
  title4 'ethlon visit information';

proc sort data=f372;
  by AID VISIT;

proc sort data=f374;
  by AID VISIT;

proc sort data=f377;
  by AID VISIT;

proc sort data=ETHLON;
  by AID VISIT;

%poplimit(dsn=finlstat);
%poplimit(dsn=f372);
%poplimit(dsn=f374);
%poplimit(dsn=f377);
%poplimit(dsn=ETHLON);

/** Add in datasets from TOMUS study for baseline variables **/
data tomus_baseline;
  set tomus.tomusbase;
  keep AID hispanic marstat v_del bmi uisurg menop any_hrt  stage stagecat ave_acc
       diffwt stress_index1 urge_index1;
run;

proc sort data = tomus_baseline;
  by AID;
run;

data tomus_f301;
  set tomus.f301;
  keep AID educ;
  format _all_;
run;

proc sort data = tomus_f301;
  by AID;
run;
```

```
data table1;
  merge finlstat(in=in_finl drop=visit) f372(in=in_f372 drop=visit) f374(in=in_f374 drop=visit) f377(in=in_f377 drop=visit) ETHLON(in=in_eth drop=visit)
        tomus_baseline(in=in_tbase rename=(bmi=baseline_bmi)) tomus_f301(in=in_f301);
  by AID;
  length V_PRO $20. MENOPAUSE $30;
  *if HEIGHT_NEW not in ('<=59' '>=69') then BMI=(WEIGHT*703)/(HEIGHT_NEW*HEIGHT_NEW);
  *if TXURGE_PRSRG=2 then PRIOR_TREAT=1;
  *else PRIOR_TREAT=0;

  /** Use POP-Q stage from baseline **/
  if stagecat = 1 then POPQ_STAGE = "Stage 0/I";
  else if stagecat = 2 then POPQ_STAGE="Stage II";
  else if stagecat = 3 then  POPQ_STAGE="Stage III/IV";

  RACE_ETHNICITY = put(hispanic, race_ethnicity.);
  EDUCATION = put(educ, education.);
  VAGINAL_NULLIPAROUS = (v_del = 0);

  /** code for combined menopause status/hrt replacement **/
  if menop = 1 then MENOPAUSE = 'Premenopausal';
  else if menop in (2,3,4) and any_hrt = 0 then MENOPAUSE = 'Postmenopausal not using HRT';
  else if menop in (2,3,4) and any_hrt = 1 then MENOPAUSE = 'Postmenopausal using HRT';

  finl_ok=in_finl;
  f372_ok=in_f372;
  f374_ok=in_f374;
  f377_ok=in_f377;
  eth_ok=in_eth;
  tbase_ok=in_tbase;
  f301_ok=in_f301;

  rename marstat=married
         uisurg=prior_ui_surgery
         diffwt=PAD_TEST
         ;


proc freq data=table1;
  tables  MENOPAUSE ave_acc / missing list;


proc freq data=table1;
  tables finl_ok*part2*f372_ok*f374_ok*f377_ok*eth_ok*tbase_ok*f301_ok/missing list;
  title3 'Merge check frequency';

*** Column processing;

data accumfreq1 accummean1 accummedian1 accuminert1;
  set _null_;

%datachunk();

data accumtab1;
  set accumfreq1 accummean1 accummedian1 accuminert1;
  if &caser=. then delete;
```

```
proc sort data=accumtab1;
  by descending &caser orderer;

proc print data=accumtab1 noobs;
  by descending &caser;
  pageby &caser;
  title3 'Table 1 stats (list)';
  where &caser in (0 1);
```

```
%let flnm = %sysfunc(getoption(sysin));
title "Program saved as: &FLNM.";
title2 "Check ETOMUS input files for DSIC";

/*************************************************************************************************************************************

Programmer: Patty Griffin
Date: March 2015

Function/Notes: Check ETOMUS input files for DSIC (Table 2)

*************************************************************************************************************************************/
*  Input files  *;
*****************;
libname inlib "/prj/niddk/ims_analysis/ETOMUS/private_orig_data/ETOMUS/Datasets";
libname tomus "/prj/niddk/public_orig_data/TOMUS_V1/3_TOMUS_Data/Data";

options nofmterr;

*************;
*  Formats  *;
*************;
proc format;
  value partfmt
    1 = "1: Yes"
    2 = "2: No, patient refused"
    3 = "3: No, unable to contact patient"
    4 = "4: No, patient refused any futur"
    5 = "5: No, other reason"
    ;
  value part2fmt
    0 = "0: No"
    1 = "1: Yes"
    ;
  value fnl_stat_cat
    1 = 'Completed Study'
    2 = 'Lost to follow-up'
    3 = 'Withdrew consent'
    4 = 'Admin decision'
    5 = 'Death'
    6 = 'Other'
    ;

 value etm_status
    1 = 'Continuing'
    2 = 'Lost'
    3 = 'Failed'
    ;

 value complete_case
   1,3 = 'Complete Case'
   2   = 'Incomplete Case'
   ;

  value lost_eq_success
  1,2 = 'Success'
```

```
  3   = 'Fail'
  ;

  value lost_eq_fail
  1 = 'Success'
  2,3 = 'Fail'
  ;


run;

%global caser;
%let caser=part2;

*******************************************************;
*  Create the report for all of the datasets in inlib  *;
*******************************************************;

data finlstat;
  set inlib.finlstat;
  if perprotocol = 1;

  complete_case = put(etm_status_60, complete_case.);

  format _all_;
run;


proc sort data=finlstat;
  by AID ;

proc freq data=finlstat;
  tables  complete_case*retropubic / missing list;
  title4 'Complete cases';
run;

proc freq data=finlstat(where=(complete_case='Complete Case'));
  tables  retropubic*etmfail_01_60 / CL;
  title4 'Complete cases';
run;

proc freq data=finlstat;
  tables  etm_status_60*retropubic ;
  format etm_status_60 lost_eq_success. ;
  title4 'Sensitivity Analyses';
run;

proc freq data=finlstat;
  tables  etm_status_60*retropubic ;
  format etm_status_60 lost_eq_fail. ;
  title4 'Sensitivity Analyses';
run;

data sensitivity2;
  *retropubic:  lost=success; *transobturator: lost=failure;
  set finlstat;
```

```
  if retropubic = 1 and etm_status_60 = 2 then etm_status_60 = 1;
  if retropubic = 0 and etm_status_60 = 2 then etm_status_60 = 3;
run;

proc freq data=sensitivity2;
  tables  etm_status_60*retropubic ;
  title4 'Sensitivity Analyses - Retropubic: lost=success';
run;

data sensitivity3;
  *retropubic:  lost=failure; *transobturator: lost=success;
  set finlstat;
  if retropubic = 1 and etm_status_60 = 2 then etm_status_60 = 3;
  if retropubic = 0 and etm_status_60 = 2 then etm_status_60 = 1;
run;

proc freq data=sensitivity3;
  tables  etm_status_60*retropubic ;
  title4 'Sensitivity Analyses - Retropubic: lost=failure';
run;
```