Dataset Integrity Check for the Folic Acid for Vascular Outcome Reduction in Transplantation Trial (FAVORIT)

Version 2 Prepared by
IMS
3901 Calverton Blvd
Calverton MD 20705
December 12, 2013

Version 1 Prepared by
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194
June 18, 2012

Revision History

Version	Author/Title	Date	Comments
1.0	SM Rogers	March 2013	Original
1.1	SM Rogers	22 April 2013	Final post-QC review
2.3	M Spriggs	16 December 2013	V2 review

Table of Contents

1 Standard Disclaimer

The Folic Acid for Vascular Outcome Reduction in Transplantation Trial (FAVORIT) was a multicenter, randomized, double-blind controlled clinical trial designed to evaluate whether treatment with folic acid and vitamins B12 and B6 reduces risk of cardiovascular disease (CVD) among clinically stable renal transplant recipients with elevated total homocysteine levels (tHcy). The FAVORIT data archive contains study data collected from screening, baseline, and follow-up for 4,110 randomized participants from 30 clinical sites. Data collection for the study began in August 2002 and follow-up ended June 2011. This Data Set Integrity Check (DSIC) consists of several analyses performed to duplicate selected results reported by Bostom et al. [1] in Circulation in 2011.

The intent of this DSIC is to provide confidence that the data distributed by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Repository is a true copy of the study data. Our intent is not to assess the integrity of the statistical analyses reported by study investigators. As with all statistical analyses of complex datasets, complete replication of a set of statistical results should not be expected on a first (or second) exercise in secondary analysis. This occurs for a number of reasons, including differences in the handling of missing data, restrictions on cases included in samples for a particular analysis, software coding used to define complex variables, and other factors. Experience suggests that most discrepancies can ordinarily be resolved by consulting 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 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

Kidney transplant recipients, like other patients with chronic kidney disease, experience excess risk of cardiovascular disease and elevated total homocysteine concentrations. The objective of the FAVORIT trial was to determine whether lowering homocysteine levels by vitamin therapy reduced the rate of pooled arteriosclerotic CVD outcomes in clinically stable kidney transplant recipients.

2.1 Study Methods

Briefly, the study was a double-blind randomized controlled trial among men and women aged 35 to 75 years who were at least 6 months post kidney transplantation. The study randomized 4,110 stable kidney transplant recipients to a multivitamin that included either a high dose of folic acid, vitamin B6, and vitamin B12 (high dose) or a multivitamin with a low dose of vitamins B6 and B12 and no folic acid (low dose). The trial enrolled patients from 30 clinical sites (27 in the U.S., two in Canada, one in Brazil) from August 2002 through January 2007. Follow-up occurred every 6 months through January 2010; mean follow-up was 4.0 years.

The primary outcome was pooled incident or recurrent CVD comprised of (1) CVD death, (2) myocardial infarction, (3) resuscitated sudden death, (4) stroke, (5) coronary artery revascularization, (6) lower extremity revascularization or amputation above the ankle for severe arterial disease, (7) carotid endarterectomy or angioplasty, (8) abdominal aortic aneurysm repair, or (9) renal artery revascularization. Secondary outcomes were all-cause mortality, dialysis-dependent kidney failure, individual and meaningful combinations of components of the primary outcome, and the number of these that occur.

3 Archived Datasets

The DCC submitted 53 SAS datasets that were reduced to 51. These 53 correspond to 41 initial datasets and an addendum of 12 datasets: The initial 41 datasets that included: 22 case report forms (CRFs) including 5 screening datasets and 17 baseline/follow-up datasets, 8 outcomes datasets, and 11 derived datasets. Derived datasets are not associated with any particular CRF but contain variables merged across several forms and/or reflect recoded variable values created by the DCC.

The addendum of 12 datasets included 2 updated versions of derived datasets, 5 baseline/follow-up datasets including one containing homocysteine, and 5 blind replica matching datasets for those 5 datasets. The earlier versions of the updated derived datasets were removed, leaving 51.

For this DSIC, we used the datasets RAND_DERV_NIDDKV2, SCREEN_DERV_NIDDKV1 RPC_NIDDKV1, LIP_NIDDKV1, ADJPROCEP_ALL_NIDDKV2 and HCYA_NIDDKV1. Contents of the archived datasets match descriptions provided in the document, NIDDK Data Dictionary V2.pdf.

4 Statistical Methods

We compared our DSIC results to the published results in:

- Table 1. Baseline Characteristics of Study Participants, and
- Figure 3. Hazard Ratios for treatment group comparisons from primary and secondary outcome subgroup analyses.

Our DSIC analyses were conducted in SAS v9 (Appendix 1). The SAS code and output used to support the findings of the DSIC appear as Appendix 1.

Baseline characteristics between treatment groups are provided in Table 1, which presents Study Ns and percentages as well as means ± standard deviations where appropriate. We note that Figure 3 of the manuscript presents primary and secondary outcomes by various population subgroups (# events/# at risk) as well as hazard ratios for treatment group comparisons. Proportional hazard models were estimated adjusting for various demographic and clinical characteristics of the respondent as well as country. The authors indicate that because of the limited effect of the vitamin treatment to normalize elevated tHcy levels, the primary analysis strategy invoked censoring at 3 months after return to long-term dialysis. This DSIC presents censored outcomes at 3-months post dialysis by subgroup.

5 Results

Variables used to replicate Table 1. **Baseline Characteristics of Study Participants** are shown in Table A. Both the dataset name and variable name are provided. The notes indicate calculations necessary to convert the stored laboratory value to the published unit.

Table A: Variables Used to Replicate Table 1.

Measure	*Dataset.variable*	*Notes*
Randomization	adjprocep_all_niddkv2.TREATHL02	
Age	rand_derv_niddkv2.AGE0101	
Sex	screen_derv_niddkv1.SPC2	
Race	rand_derv_niddkv2.RACE0107	
Location	screen_derv_niddkv1.COUNTRY0001	
Graft vintage	rand_derv_niddkv2.GVINTAGEYR0101	
History of CVD	rand_derv_niddkv2.CVD0101	
History of DM	rand_derv_niddkv2.DIAB0104	
Prevalent hypertension	rand_derv_niddkv2.HTN0101	
BMI	rand_derv_niddkv2.BMI0102	
Current smoker	rpc_niddkv1.RPC5A	
Total cholesterol	lip_niddkv1.LIP1A	divide by 39
High-density lipoprotein cholesterol	lip_niddkv1.LIP1C	divide by 39
Calculated or low-density cholesterol	rand_derv_niddkv2.LDL _D0104	
Triglycerides	lip_niddkv1.LIP1B	divide by 89
Screening homocysteine	hcya_niddkv1.HCYA1	
Screening creatinine	screen_derv_niddkv1.CREA0002	multiply by 88.4
Screening eGFR	screen_derv_niddkv1.GFR0008	
CKD stage	screen_derv_niddkv1.CKDST0005	

DSIC Results: Table 1. The published manuscript results and the DSIC results for Table 1 are shown below (Table B). The base Ns and mean values for the baseline patient characteristics and histology results calculated by the DSIC correspond to published values, with the only consequential discrepancies occurring in the standard deviations of Screening homocysteine.

Table B: Table 1. Baseline Characteristics of Study Participants.

Characteristic	*Bostom et al (2011)*			DSIC		
	Overall (n=4110)	**High Dose (n=2056)**	**Low Dose (n=2054)**	**Overall (n=4110)**	**High Dose‡ (n=2056)**	**Low Dose‡ (n=2054)**
Age, y	52±9.4	52±9.4	52±9.4	52±9.4	52±9.4	52±9.5
Female sex, n (%)	1528 (37.2)	767 (37.3)	761 (37.0)	1528 (37.2)	767 (37.3)	761 (37.0)
Nonwhite race, n (%)	945 (23.5)	477 (23.7)	468 (23.3)	998 (24.5)	508(24.9)	490 (24.0)
Location, n (%)						
Brazil	612 (14.9)	307 (14.9)	305 (14.8)	612 (14.9)	307 (14.9)	305 (14.8)
Canada	498 (12.1)	249 (12.1)	249 (12.1)	498 (12.1)	249 (12.1)	249 (12.1)
United States	3000 (73.0)	1500 (73)	1500 (73)	3000 (73.0)	1500 (73)	1500 (73)
Graft vintage, y	5±5.0	6 ± 5.1	5±5.0	5.5±5.0	5.5 ± 5.1	5.4±5.0
History of CVD, n (%)	820 (20.0)	406 (19.8)	414 (20.3)	820 (20.0)	406 (19.8)	414 (20.3)
History of DM, n (%)	1663 (40.5)	813 (39.6)	850 (41.5)	1663 (40.5)	813 (39.6)	850 (41.5)
Prevalent hypertension, n (%)	3778 (92.0)	1879 (91.5)	1899 (92.5)	3778 (92.0)	1879 (91.5)	1899 (92.5)
BMI, kg/m2	29 ±6.2	29 ±6.2	29 ±6.3	29 ±6.2	29 ±6.2	29 ±6.2
Current smoker, n (%)	451 (11.1)	230 (11.3)	221 (10.9)	451 (11.1)	230 (11.3)	221 (10.9)
Total cholesterol, mmol/L	4.8±1.1	4.8 ± 1.2	4.8±1.1	4.7±1.1	4.8 ± 1.1	4.7±1.1
High-density lipoprotein cholesterol, mmol/L	1.2 ±0.4	1.2 ± 0.4	1.2 ± 0.4	1.2 ±0.4	1.2 ± 0.4	1.2 ± 0.4
Calculated or direct low-density cholesterol, mmol/L	2.6 ±0.9	2.6 ±0.9	2.6 ±0.9	2.6 ±0.9	2.6 ±0.9	2.6 ±0.9
Triglycerides, mmol/L	2.2 ±2.1	2.3 ± 2.5	2.2±1.6	2.2 ±2.0	2.3 ± 2.4	2.2±1.5
Screening homocysteine	16.4 ±1.3	16.4 ±1.3	16.4 ±1.3	17.1±6.3	17.1±6.6	17.1±6.0
Female	16.8 ± 1.3	17 ± 1.3	16.7 ± 1.3	16.2±5.8	15.9±4.8	16.6±6.6
Male	15.6 ± 1.3	15.3 ± 1.3	15.8 ± 1.3	17.6±6.5	17.8±7.3	17.3±5.5
Screening creatinine, µmol/L	144.3 ±42.1	145 ± 42.5	143.6 ± 41.6	144.3 ±42.1	145 ± 42.5	143.6 ± 41.6
Screening (eGFR mL/min per 1.73 m)	48.8 ± 16.2	48.5 ± 15.9	49 ± 16.5	48.8 ± 16.2	48.6 ± 16.0	49.1 ± 16.5
CKD stage, n (%)*						
Stage 1T (eGFR 90+ mL/min per 1.73 m2)	69 (1.7)	28 (1.4)	41 (2.0)	73 (1.8)	30 (1.5)	43 (2.1)
Stage 1T (eGFR 60-89 mL/min per 1.73 m2)	819 (20.4)	405 (20.1)	414 (20.6)	840 (20.4)	418 (20.3)	422 (20.6)
Stage 1T (eGFR 30-59 mL/min per 1.73 m2)	2738 (68.1)	1380 (68.7)	1358 (67.5)	2795 (68.0)	1406 (68.4)	1389 (67.6)
Stage 1T (eGFR 15-29 mL/min per 1.73 m2)	394 (9.8)	197 (9.8)	197 (9.8)	401 (9.8)	202 (9.8)	199 (9.7)
Stage 1T (eGFR <15 mL/min per 1.73 m2)	1 (0.0)	0	1 (0.0)	1 (0.0)	0	1 (0.0)

* Based on CKD-EPI eGFR formula.

Data presented as mean ± standard deviation.

CVD = cardiovascular disease; eGFR = estimated glomular filtration rate; CKD = chronic kidney disease.

‡ Sample Ns vary from 1,948 to 2,056 for High Dose participants and 1,957 to 2,054 for Low Dose participants.

DSIC Results. Figure 3. Figure 3 of the manuscript presents primary and secondary outcome subgroup analyses. Outcomes include primary CVD endpoint, all-cause mortality, and dialysis-dependent kidney failure and are tabulated by age, sex, race, and history of diabetes. Results of these subgroup analyses failed to demonstrate a treatment effect. Our DSIC estimates were derived from the datasets rand_derv_niddkv2,screen_derv_niddkv1, rpc_niddkv1, lip_niddkv1, adjprocep_all_niddkv2 andhcya_niddkv1, and are presented with the manuscript results in Table C. Our DSIC analyses are consistent with the published results for the number of events/number at risk for each subgroup with only inconsequential discrepancies.

Table C: Results from Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses.

Primary CVD Endpoint	***Bostom et al (2011)***		**DSIC**	
Characteristic	**High Dose**	**Low Dose**	**High Dose**	**Low Dose**
	# Events/# At Risk	**# Events/# At Risk**	**# Events/# At Risk**	**# Events/# At Risk**
Age, years				
<60	178/1573 (11.3%)	186/1578 (11.8%)	178/1594 (11.2%)	186/1597 (11.6%)
≥60	91/456 (20%)	92/451 (20.4%	91/462 (19.7%)	92/457 (20.1%)
Sex				
Female	90/755 (11.9%)	85/752 (11.3%)	90/767 (11.7%)	85/761 (11.2%)
Male	179/1274 (14.1%)	193/1277 (15.1%)	179/1289 (13.9%)	193/1293 (14.9%)
Race				
Nonwhite	54/467 (11.6%)	54/460 (11.7%)	58/508 (11.4%)	58/490 (11.8%)
White	209/1518 (13.8%)	219/1527 (14.3%)	209/1534 (13.6%)	219/1550 (14.1%)
History of Diabetes				
Nondiabetic	99/1224 (8.1%)	89/1186 (7.5%)	99/1242 (8.0%)	89/1198 (7.4%)
Diabetic	170/805 (21.1%)	189/843 (22.4%)	170/813 (20.9%)	189/850 (22.2%)
Screening tHcy				
<19.0 (75%tile)	193/1520(12.7%)	190/1513(12.6%)	194/1539(12.6%)	194/1539(12.6%)
>=19.0 (75%tile)	76/509(14.9%)	88/516(17.1%)	75/517(14.5%)	84/515(16.3%)
All-Cause Mortality				
Age, years				
<60	124/1592 (7.8%)	133/1592 (8.4%)	124/1594 (7.8%)	133/1597 (8.3%)
≥60	93/482 (20.1%)	81/457 (17.7%)	93/462 (20.1%)	81/457 (17.7%)
Sex				
Female	79/766 (10.3%)	78/759 (10.3%)	79/767 (10.3%)	78/761 (10.2%)
Male	138/1288 (10.7%)	136/1290 (10.5%)	138/1289 (10.7%)	136/1293 (10.5%)
Race				
Nonwhite	51/475 (10.7%)	50/468 (10.7%)	56/508 (11.0%)	51/490 (10.4%)
White	159/1533 (10.4%)	162/1539 (10.5%)	159/1534 (10.4%)	162/1550 (10.5%)
History of Diabetes				
Nondiabetic	91/1241 (7.3%)	80/1200 (6.7%)	91/1242 (7.3%)	80/1198 (6.7%)
Diabetic	125/813 (15.5%)	134/849 (15.8%)	126/813 (15.5%)	134/850 (15.8%)
Screening tHcy				
<19.0 (75%tile)	147/1540(9.5%)	131/1529(8.6%)	150/1539(9.7%)	134/1539(8.7%)
>=19.0 (75%tile)	70/514(13.6%)	83/520(16.0%)	67/517(13.0%)	80/515(15.5%)

Primary CVD Endpoint	***Bostom et al (2011)***		**DSIC**	
Characteristic	**High Dose**	**Low Dose**	**High Dose**	**Low Dose**
	# Events/# At Risk	**# Events/# At Risk**	**# Events/# At Risk**	**# Events/# At Risk**
Dialysis-Dependent Kidney Failure				
Age, years				
<60	152/1573 (9.7%)	144/1579 (9.1%)	152/1594 (9.5%)	144/1597 (9.0%)
≥60	29/456 (6.4%)	18/451 (4%)	29/462 (6.3%)	18/457 (3.9%)
Sex				
Female	67/755 (8.9%0	54/752 (7.2%)	67/767 (8.7%)	54/761 (7.1%)
Male	114/1274 (8.9%)	108/1277 (8.5%)	114/1289 (8.8%)	108/1293 (8.4%)
Race				
Nonwhite	51/467 (10.9%)	49/460 (10.7%)	56/508 (11.0%)	49/490 (10%)
White	123/1518 (8.1%)	112/1527 (7.3%)	123/1534 (8.0%)	112/1550 (7.2%)
History of Diabetes				
Nondiabetic	108/1224 (8.8%)	81/1186 (6.8%)	107/1242 (8.6%)	81/1198 (6.8%)
Diabetic	73/805 (9.1%)	81/843 (9.6%)	73/813 (9.0%)	81/850 (9.5%)
Screening tHcy				
<19.0 (75%tile)	115/1520(7.6%)	100/1513(6.6%)	113/1539(7.3%)	102/1539(6.6%)
>=19.0 (75%tile)	66/509(13.0%)	62/516(12.0%)	68/517(13.2%)	60/515(11.7%)

6 Conclusions

The results of these DSIC analyses provide confidence that the FAVORIT data distributed by the NIDDK repository are a true copy of the study data.

7 References

Bostom AG, MA Carpenter, JW Kusek et al. (2011). Homocysteine-Lowering and Cardiovascular Disease Outcomes in Kidney Transplant Recipients: Primary results from the folic acid for vascular outcome reduction in transplantation trial. *Circulation* 123:1763-1770.

Appendix 1. SAS Output used to Replicate Manuscript Results.

```
title1 "%sysfunc(getoption(sysin))";
title2 " ";

options nofmterr mprint source2;

libname vtwodata
"/prj/niddk/ims_analysis/FAVORIT/private_created_data/FAVORIT_V2/FAVORIT_Ver2/Data/
";

data rand_derv_niddkv2    ; set vtwodata.rand_derv_niddkv2     ;
data adjprocep_all_niddkv2; set vtwodata.adjprocep_all_niddkv2 ;
data screen_derv_niddkv1  ; set vtwodata.screen_derv_niddkv1   ;
data rpc_niddkv1          ; set vtwodata.rpc_niddkv1           ;
data lip_niddkv1          ; set vtwodata.lip_niddkv1           ;
data hcya_niddkv1         ; set vtwodata.hcya_niddkv1          ;

*** configure Proc freq to match format used in output table ****;
ods path(prepend) work.templat(update);
proc format;
picture pctfmt (round) other='009.9%';
run;
proc template;
define crosstabs Base.Freq.CrossTabFreqs;
cellvalue frequency percent rowpercent colpercent;
define frequency;
format=8.;
header='Count';
end;
define percent;
format=pctfmt.;
header='Overall %';
end;
define rowpercent;
format=pctfmt.;
header='Row %';
end;
define colpercent;
format=pctfmt.;
header='Col %';
end;
end;
run;

proc format;
  value sixtyf
  0-<60="<60"
  60-high="60+"
  ;
  value hihcy
  0-<19='<19.0 (75%tile)'
  19-high='>=19.0 (75%tile)'
  ;
data DSIC;
  merge rand_derv_niddkv2(keep=BLINDID AGE0101 RACE0107 GVINTAGEYR0101 CVD0101
DIAB0104 HTN0101 BMI0102 LDL_D0104)
        screen_derv_niddkv1(keep=BLINDID CREA0002 SPC2 COUNTRY0001 GFR0008
CKDST0005)
        rpc_niddkv1(keep=BLINDID RPC5A)
        lip_niddkv1(keep=BLINDID LIP1A LIP1B LIP1C)
        adjprocep_all_niddkv2(keep=BLINDID TREATHL02 ADJPROCFEVT_DIAA01
DIALYSIS_FEVT01 TOTAL_MORT_FEVT_DIAA01)
        hcya_niddkv1(keep=BLINDID VISIT HCYA1)
        ;
  by BLINDID;
  LIP1A_MOD=LIP1A/39;
  LIP1B_MOD=LIP1B/89;
  LIP1C_MOD=LIP1C/39;
```

```
  CREA0002_MOD=CREA0002*88.4;
  if TREATHL02 ne ' ' and VISIT=0 then output;

title2 'All tables limited to 4110 records with a value for TREATHL02 and
Homocysteine Visit=0';

*** Table 1 ****;

proc means data=DSIC n mean stddev maxdec=1 print;
  var AGE0101;
  class TREATHL02;
  types ()(TREATHL02);
  title3 'Table 1. Baseline Characteristics of Study Participants (AGE).';

proc freq data=DSIC;
  tables TREATHL02*SPC2/nocol;
  title3 'Table 1. Baseline Characteristics of Study Participants (SEX).';

proc freq data=DSIC;
  tables TREATHL02*RACE0107/nocol;
  title3 'Table 1. Baseline Characteristics of Study Participants (RACE).';

proc freq data=DSIC;
  tables TREATHL02*COUNTRY0001/nocol;
  title3 'Table 1. Baseline Characteristics of Study Participants (LOCATION).';

proc means data=DSIC n mean stddev maxdec=1 print;
  var GVINTAGEYR0101;
  class TREATHL02;
  types ()(TREATHL02);
  title3 'Table 1. Baseline Characteristics of Study Participants (GRAFT
VINTAGE).';

proc freq data=DSIC;
  tables TREATHL02*CVD0101/nocol;
  title3 'Table 1. Baseline Characteristics of Study Participants (CVD).';

proc freq data=DSIC;
  tables TREATHL02*DIAB0104/nocol;
  title3 'Table 1. Baseline Characteristics of Study Participants (DM).';

proc freq data=DSIC;
  tables TREATHL02*HTN0101/nocol;
  title3 'Table 1. Baseline Characteristics of Study Participants (HYPERTENSION).';

proc means data=DSIC n mean stddev maxdec=1 print;
  var BMI0102;
  class TREATHL02;
  types ()(TREATHL02);
  title3 'Table 1. Baseline Characteristics of Study Participants (BMI).';

proc freq data=DSIC;
  tables TREATHL02*RPC5A/nocol;
  title3 'Table 1. Baseline Characteristics of Study Participants (CURRENT
SMOKER).';

proc means data=DSIC n mean stddev maxdec=1 print;
  var LIP1A_MOD;
  class TREATHL02;
  types ()(TREATHL02);
  title3 'Table 1. Baseline Characteristics of Study Participants (TOTAL
CHOLESTEROL).';

proc means data=DSIC n mean stddev maxdec=1 print;
  var LIP1C_MOD;
  class TREATHL02;
  types ()(TREATHL02);
  title3 'Table 1. Baseline Characteristics of Study Participants (HIGH DENSITY
LIPOPROTEIN CHOLESTEROL).';

proc means data=DSIC n mean stddev maxdec=1 print;
  var LDL_D0104;
  class TREATHL02;
```

```
  types ()(TREATHL02);
  title3 'Table 1. Baseline Characteristics of Study Participants (CALCULATED OR
LOW DENSITY CHOLESTEROL).';

proc means data=DSIC n mean stddev maxdec=1 print;
  var LIP1B_MOD;
  class TREATHL02;
  types ()(TREATHL02);
  title3 'Table 1. Baseline Characteristics of Study Participants
(TRIGLYCERIDES).';

proc means data=DSIC n mean stddev p25 p75 maxdec=1 print;
  var HCYA1;
  class TREATHL02 SPC2;
  types ()(TREATHL02)(SPC2);
  title3 'Table 1. Baseline Characteristics of Study Participants (SCREENING
HOMOCYSTEINE [individually]).';

proc means data=DSIC n mean stddev p25 p75 maxdec=1 print;
  var HCYA1;
  class TREATHL02 SPC2;
  title3 'Table 1. Baseline Characteristics of Study Participants (SCREENING
HOMOCYSTEINE [together]).';

proc means data=DSIC n mean stddev maxdec=1 print;
  var CREA0002_MOD;
  class TREATHL02;
  types ()(TREATHL02);
  title3 'Table 1. Baseline Characteristics of Study Participants (CREATINE).';

proc means data=DSIC n mean stddev maxdec=1 print;
  var GFR0008;
  class TREATHL02;
  types ()(TREATHL02);
  title3 'Table 1. Baseline Characteristics of Study Participants (EGFR).';

proc freq data=DSIC;
  tables TREATHL02*CKDST0005/nocol;
  title3 'Table 1. Baseline Characteristics of Study Participants (CKD).';

*** Figure 3 ****;

proc sort data=DSIC;
  by TREATHL02;

proc freq data=DSIC;
  tables AGE0101*ADJPROCFEVT_DIAA01/nocol;
  by TREATHL02;
  format AGE0101 sixtyf.;
  title3 'Figure 3. Hazard ratios for treatment group comparisons from primary and
secondary outcome subgroup analyses - Primary CVD Endpoint (AGE).';

proc freq data=DSIC;
  tables SPC2*ADJPROCFEVT_DIAA01/nocol;
  by TREATHL02;
  title3 'Figure 3. Hazard ratios for treatment group comparisons from primary and
secondary outcome subgroup analyses - Primary CVD Endpoint (SEX).';

proc freq data=DSIC;
  tables RACE0107*ADJPROCFEVT_DIAA01/nocol;
  by TREATHL02;
  title3 'Figure 3. Hazard ratios for treatment group comparisons from primary and
secondary outcome subgroup analyses - Primary CVD Endpoint (RACE).';

proc freq data=DSIC;
  tables DIAB0104*ADJPROCFEVT_DIAA01/nocol;
  by TREATHL02;
  title3 'Figure 3. Hazard ratios for treatment group comparisons from primary and
secondary outcome subgroup analyses - Primary CVD Endpoint (DM).';

proc freq data=DSIC;
  tables HCYA1*ADJPROCFEVT_DIAA01/nocol;
  by TREATHL02;
```

```
  format HCYA1 hihcy.;
  title3 'Figure 3. Hazard ratios for treatment group comparisons from primary and
secondary outcome subgroup analyses - Primary CVD Endpoint (HCY).';

proc freq data=DSIC;
  tables AGE0101*TOTAL_MORT_FEVT_DIAA01/nocol;
  by TREATHL02;
  format AGE0101 sixtyf.;
  title3 'Figure 3. Hazard ratios for treatment group comparisons from primary and
secondary outcome subgroup analyses - All Cause Mortality (AGE).';

proc freq data=DSIC;
  tables SPC2*TOTAL_MORT_FEVT_DIAA01/nocol;
  by TREATHL02;
  title3 'Figure 3. Hazard ratios for treatment group comparisons from primary and
secondary outcome subgroup analyses - All Cause Mortality (SEX).';

proc freq data=DSIC;
  tables RACE0107*TOTAL_MORT_FEVT_DIAA01/nocol;
  by TREATHL02;
  title3 'Figure 3. Hazard ratios for treatment group comparisons from primary and
secondary outcome subgroup analyses - All Cause Mortality (RACE).';

proc freq data=DSIC;
  tables DIAB0104*TOTAL_MORT_FEVT_DIAA01/nocol;
  by TREATHL02;
  title3 'Figure 3. Hazard ratios for treatment group comparisons from primary and
secondary outcome subgroup analyses - All Cause Mortality (DM).';

proc freq data=DSIC;
  tables HCYA1*TOTAL_MORT_FEVT_DIAA01/nocol;
  by TREATHL02;
  format HCYA1 hihcy.;
  title3 'Figure 3. Hazard ratios for treatment group comparisons from primary and
secondary outcome subgroup analyses - All Cause Mortality (HCY).';

proc freq data=DSIC;
  tables AGE0101*DIALYSIS_FEVT01/nocol;
  by TREATHL02;
  format AGE0101 sixtyf.;
  title3 'Figure 3. Hazard ratios for treatment group comparisons from primary and
secondary outcome subgroup analyses - Dialysis (AGE).';

proc freq data=DSIC;
  tables SPC2*DIALYSIS_FEVT01/nocol;
  by TREATHL02;
  title3 'Figure 3. Hazard ratios for treatment group comparisons from primary and
secondary outcome subgroup analyses - Dialysis (SEX).';

proc freq data=DSIC;
  tables RACE0107*DIALYSIS_FEVT01/nocol;
  by TREATHL02;
  title3 'Figure 3. Hazard ratios for treatment group comparisons from primary and
secondary outcome subgroup analyses - Dialysis (RACE).';

proc freq data=DSIC;
  tables DIAB0104*DIALYSIS_FEVT01/nocol;
  by TREATHL02;
  title3 'Figure 3. Hazard ratios for treatment group comparisons from primary and
secondary outcome subgroup analyses - Dialysis (DM).';

proc freq data=DSIC;
  tables HCYA1*DIALYSIS_FEVT01/nocol;
  by TREATHL02;
  format HCYA1 hihcy.;
  title3 'Figure 3. Hazard ratios for treatment group comparisons from primary and
secondary outcome subgroup analyses - Dialysis (HCY).';
```

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 1
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine
Visit=0
Table 1. Baseline Characteristics of Study Participants (AGE).

The MEANS Procedure

Analysis Variable : AGE0101 AGE, V1

N Obs	N	Mean	Std Dev
4110	4110	51.9	9.4

Analysis Variable : AGE0101 AGE, V1

Treatment Group Assignment	N Obs	N	Mean	Std Dev
HIGH	2056	2056	51.8	9.4
LOW	2054	2054	52.0	9.5

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 2
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine
Visit=0
Table 1. Baseline Characteristics of Study Participants (SEX).

The FREQ Procedure

Count / Overall % / Row %	F	M	Total
HIGH	767	1289	2056
	18.7%	31.4%	50.0%
	37.3%	62.7%	
LOW	761	1293	2054
	18.5%	31.5%	50.0%
	37.0%	63.0%	
Total	1528	2582	4110
	37.2%	62.8%	100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 3
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine
Visit=0
Table 1. Baseline Characteristics of Study Participants (RACE).

The FREQ Procedure

Count Overall % Row %	Non-White	White	Total
HIGH	508 12.4% 24.9%	1534 37.6% 75.1%	2042 50.0%
LOW	490 12.0% 24.0%	1550 38.0% 76.0%	2040 50.0%
Total	998 24.4%	3084 75.6%	4082 100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 4
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine
Visit=0
Table 1. Baseline Characteristics of Study Participants (LOCATION).

The FREQ Procedure

Count Overall % Row %	1	2	3	Total
HIGH	1500 36.5% 73.0%	249 6.1% 12.1%	307 7.5% 14.9%	2056 50.0%
LOW	1500 36.5% 73.0%	249 6.1% 12.1%	305 7.4% 14.8%	2054 50.0%
Total	3000 73.0%	498 12.1%	612 14.9%	4110 100.0%

All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Table 1. Baseline Characteristics of Study Participants (GRAFT VINTAGE).

The MEANS Procedure

Analysis Variable : GVINTAGEYR0101 CURRENT GRAFT VINTAGE IN YRS

N Obs	N	Mean	Std Dev
4110	4090	5.5	5.0

Analysis Variable : GVINTAGEYR0101 CURRENT GRAFT VINTAGE IN YRS

Treatment Group Assignment	N Obs	N	Mean	Std Dev
HIGH	2056	2044	5.5	5.1
LOW	2054	2046	5.4	5.0

All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Table 1. Baseline Characteristics of Study Participants (CVD).

The FREQ Procedure

Count / Overall % / Row %	0	1	Total
HIGH	1649 40.3% 80.2%	406 9.9% 19.8%	2055 50.2%
LOW	1626 39.7% 79.7%	414 10.1% 20.3%	2040 49.8%
Total	3275 80.0%	820 20.0%	4095 100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 7
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine
Visit=0
Table 1. Baseline Characteristics of Study Participants (DM).

The FREQ Procedure

Count / Overall % / Row %	N	Y	Total
HIGH	1242	813	2055
	30.3%	19.8%	50.1%
	60.4%	39.6%	
LOW	1198	850	2048
	29.2%	20.7%	49.9%
	58.5%	41.5%	
Total	2440	1663	4103
	59.5%	40.5%	100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 8
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine
Visit=0
Table 1. Baseline Characteristics of Study Participants (HYPERTENSION).

The FREQ Procedure

Count / Overall % / Row %	0	1	Total
HIGH	175	1879	2054
	4.3%	45.8%	50.0%
	8.5%	91.5%	
LOW	153	1899	2052
	3.7%	46.2%	50.0%
	7.5%	92.5%	
Total	328	3778	4106
	8.0%	92.0%	100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 9
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine
Visit=0
Table 1. Baseline Characteristics of Study Participants (BMI).

The MEANS Procedure

Analysis Variable : BMI0102 BODY MASS INDEX, USING DERIVED HT AND WT (KG/(M
SQUARED)), V1

N Obs	N	Mean	Std Dev
4110	3989	29.1	6.2

Analysis Variable : BMI0102 BODY MASS INDEX, USING DERIVED HT AND WT (KG/(M
SQUARED)), V1

Treatment Group Assignment	N Obs	N	Mean	Std Dev
HIGH	2056	1998	29.1	6.2
LOW	2054	1991	29.2	6.2

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 10
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine
Visit=0
Table 1. Baseline Characteristics of Study Participants (CURRENT SMOKER).

The FREQ Procedure

Count / Overall % / Row %	A	B	C	Total
HIGH	973	230	827	2030
	23.9%	5.7%	20.4%	50.0%
	47.9%	11.3%	40.7%	
LOW	1028	221	784	2033
	25.3%	5.4%	19.3%	50.0%
	50.6%	10.9%	38.6%	
Total	2001	451	1611	4063
	49.2%	11.1%	39.7%	100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 11
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine
Visit=0
Table 1. Baseline Characteristics of Study Participants (TOTAL CHOLESTEROL).

The MEANS Procedure

Analysis Variable : LIP1A_MOD

N Obs	N	Mean	Std Dev
4110	3914	4.7	1.1

Analysis Variable : LIP1A_MOD

Treatment Group Assignment	N Obs	N	Mean	Std Dev
HIGH	2056	1955	4.8	1.1
LOW	2054	1959	4.7	1.1

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 12
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine
Visit=0
Table 1. Baseline Characteristics of Study Participants (HIGH DENSITY LIPOPROTEIN CHOLESTEROL).

The MEANS Procedure

Analysis Variable : LIP1C_MOD

N Obs	N	Mean	Std Dev
4110	3914	1.2	0.4

Analysis Variable : LIP1C_MOD

Treatment Group Assignment	N Obs	N	Mean	Std Dev
HIGH	2056	1955	1.2	0.4
LOW	2054	1959	1.2	0.4

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 13
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine
Visit=0
Table 1. Baseline Characteristics of Study Participants (CALCULATED OR LOW DENSITY CHOLESTEROL).

The MEANS Procedure

Analysis Variable : LDL_D0104 Derived from Direct LDL (mmol/L) if Trig mg/dl > 400 and Calculated LDL (mmol/L) if Trig mg/dl <=400, version 4

N Obs	N	Mean	Std Dev
4110	3910	2.6	0.9

Analysis Variable : LDL_D0104 Derived from Direct LDL (mmol/L) if Trig mg/dl > 400 and Calculated LDL (mmol/L) if Trig mg/dl <=400, version 4

Treatment Group Assignment	N Obs	N	Mean	Std Dev
HIGH	2056	1953	2.6	0.9
LOW	2054	1957	2.6	0.9

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 14
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine
Visit=0
Table 1. Baseline Characteristics of Study Participants (TRIGLYCERIDES).

The MEANS Procedure

Analysis Variable : LIP1B_MOD

N Obs	N	Mean	Std Dev
4110	3914	2.2	2.0

Analysis Variable : LIP1B_MOD

Treatment Group Assignment	N Obs	N	Mean	Std Dev
HIGH	2056	1955	2.3	2.4
LOW	2054	1959	2.2	1.5

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 15
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Table 1. Baseline Characteristics of Study Participants (SCREENING HOMOCYSTEINE [individually]).

The MEANS Procedure

Analysis Variable : HCYA1 THCY VALUE - UMOL/L (HCYA1)

N Obs	N	Mean	Std Dev	25th Pctl	75th Pctl
4110	4110	17.1	6.3	13.3	19.0

Analysis Variable : HCYA1 THCY VALUE - UMOL/L (HCYA1)

GENDER (SPC2) DERIVE VARIABLE IS IDENTICAL TO SPC ITEM 2	N Obs	N	Mean	Std Dev	25th Pctl	75th Pctl
F	1528	1528	16.2	5.8	12.7	17.9
M	2582	2582	17.6	6.5	13.7	19.6

Analysis Variable : HCYA1 THCY VALUE - UMOL/L (HCYA1)

Treatment Group Assignment	N Obs	N	Mean	Std Dev	25th Pctl	75th Pctl
HIGH	2056	2056	17.1	6.6	13.3	19.0
LOW	2054	2054	17.1	6.0	13.3	19.0

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 16
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Table 1. Baseline Characteristics of Study Participants (SCREENING HOMOCYSTEINE [together]).

The MEANS Procedure

Analysis Variable : HCYA1 THCY VALUE - UMOL/L (HCYA1)

Treatment Group Assignment	GENDER (SPC2) DERIVE VARIABLE IS IDENTICAL TO SPC ITEM 2	N Obs	N	Mean	Std Dev	25th Pctl	75th Pctl
HIGH	F	767	767	15.9	4.8	12.6	17.5
	M	1289	1289	17.8	7.3	13.8	19.7
LOW	F	761	761	16.6	6.6	12.8	18.3
	M	1293	1293	17.3	5.5	13.6	19.4

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 17
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Table 1. Baseline Characteristics of Study Participants (CREATINE).

The MEANS Procedure

Analysis Variable : CREA0002_MOD

N Obs	N	Mean	Std Dev
4110	4110	144.3	42.1

Analysis Variable : CREA0002_MOD

Treatment Group Assignment	N Obs	N	Mean	Std Dev
HIGH	2056	2056	145.0	42.5
LOW	2054	2054	143.6	41.6

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 18
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine
Visit=0
Table 1. Baseline Characteristics of Study Participants (EGFR).

The MEANS Procedure

Analysis Variable : GFR0008 CKD_EPI for estimating GFR, external adjustment

N Obs	N	Mean	Std Dev
4110	4110	48.8	16.2

Analysis Variable : GFR0008 CKD_EPI for estimating GFR, external adjustment

Treatment Group Assignment	N Obs	N	Mean	Std Dev
HIGH	2056	2056	48.6	16.0
LOW	2054	2054	49.1	16.5

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 19
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine
Visit=0
Table 1. Baseline Characteristics of Study Participants (CKD).

The FREQ Procedure

Count / Overall % / Row %	1	2	3	4	5	Total
HIGH	30	418	1406	202	0	2056
	0.7%	10.2%	34.2%	4.9%	0.0%	50.0%
	1.5%	20.3%	68.4%	9.8%	0.0%	
LOW	43	422	1389	199	1	2054
	1.0%	10.3%	33.8%	4.8%	0.0%	50.0%
	2.1%	20.5%	67.6%	9.7%	0.0%	
Total	73	840	2795	401	1	4110
	1.8%	20.4%	68.0%	9.8%	0.0%	100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 20
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - Primary CVD Endpoint (AGE).

Treatment Group Assignment=HIGH

The FREQ Procedure

Count / Overall % / Row %	0	1	Total
<60	1416	178	1594
	68.9%	8.7%	77.5%
	88.8%	11.2%	
60+	371	91	462
	18.0%	4.4%	22.5%
	80.3%	19.7%	
Total	1787	269	2056
	86.9%	13.1%	100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 21
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - Primary CVD Endpoint (AGE).

Treatment Group Assignment=LOW

The FREQ Procedure

Count / Overall % / Row %	0	1	Total
<60	1411	186	1597
	68.7%	9.1%	77.8%
	88.4%	11.6%	
60+	365	92	457
	17.8%	4.5%	22.2%
	79.9%	20.1%	
Total	1776	278	2054
	86.5%	13.5%	100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 22
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - Primary CVD Endpoint (SEX).

Treatment Group Assignment=HIGH

The FREQ Procedure

Count / Overall % / Row %	0	1	Total
F	677 32.9% 88.3%	90 4.4% 11.7%	767 37.3%
M	1110 54.0% 86.1%	179 8.7% 13.9%	1289 62.7%
Total	1787 86.9%	269 13.1%	2056 100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 23
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - Primary CVD Endpoint (SEX).

Treatment Group Assignment=LOW

The FREQ Procedure

Count / Overall % / Row %	0	1	Total
F	676 32.9% 88.8%	85 4.1% 11.2%	761 37.0%
M	1100 53.6% 85.1%	193 9.4% 14.9%	1293 63.0%
Total	1776 86.5%	278 13.5%	2054 100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 24
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - Primary CVD Endpoint (RACE).

Treatment Group Assignment=HIGH

The FREQ Procedure

Count / Overall % / Row %	0	1	Total
Non-White	450	58	508
	22.0%	2.8%	24.9%
	88.6%	11.4%	
White	1325	209	1534
	64.9%	10.2%	75.1%
	86.4%	13.6%	
Total	1775	267	2042
	86.9%	13.1%	100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 25
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - Primary CVD Endpoint (RACE).

Treatment Group Assignment=LOW

The FREQ Procedure

Count / Overall % / Row %	0	1	Total
Non-White	432	58	490
	21.2%	2.8%	24.0%
	88.2%	11.8%	
White	1331	219	1550
	65.2%	10.7%	76.0%
	85.9%	14.1%	
Total	1763	277	2040
	86.4%	13.6%	100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 26
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - Primary CVD Endpoint (DM).

Treatment Group Assignment=HIGH

The FREQ Procedure

Count / Overall % / Row %	0	1	Total
N	1143 55.6% 92.0%	99 4.8% 8.0%	1242 60.4%
Y	643 31.3% 79.1%	170 8.3% 20.9%	813 39.6%
Total	1786 86.9%	269 13.1%	2055 100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 27
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - Primary CVD Endpoint (DM).

Treatment Group Assignment=LOW

The FREQ Procedure

Count / Overall % / Row %	0	1	Total
N	1109 54.2% 92.6%	89 4.3% 7.4%	1198 58.5%
Y	661 32.3% 77.8%	189 9.2% 22.2%	850 41.5%
Total	1770 86.4%	278 13.6%	2048 100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 28
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - Primary CVD Endpoint (HCY).

Treatment Group Assignment=HIGH

The FREQ Procedure

Count Overall % Row %	0	1	Total
<19.0 (75%tile)	1345 65.4% 87.4%	194 9.4% 12.6%	1539 74.9%
>=19.0 (75%tile)	442 21.5% 85.5%	75 3.6% 14.5%	517 25.1%
Total	1787 86.9%	269 13.1%	2056 100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 29
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - Primary CVD Endpoint (HCY).

Treatment Group Assignment=LOW

The FREQ Procedure

Count Overall % Row %	0	1	Total
<19.0 (75%tile)	1345 65.5% 87.4%	194 9.4% 12.6%	1539 74.9%
>=19.0 (75%tile)	431 21.0% 83.7%	84 4.1% 16.3%	515 25.1%
Total	1776 86.5%	278 13.5%	2054 100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 30
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - All Cause Mortality (AGE).

Treatment Group Assignment=HIGH

The FREQ Procedure

Count / Overall % / Row %	0	1	Total
<60	1470	124	1594
	71.5%	6.0%	77.5%
	92.2%	7.8%	
60+	369	93	462
	17.9%	4.5%	22.5%
	79.9%	20.1%	
Total	1839	217	2056
	89.4%	10.6%	100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 31
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - All Cause Mortality (AGE).

Treatment Group Assignment=LOW

The FREQ Procedure

Count / Overall % / Row %	0	1	Total
<60	1464	133	1597
	71.3%	6.5%	77.8%
	91.7%	8.3%	
60+	376	81	457
	18.3%	3.9%	22.2%
	82.3%	17.7%	
Total	1840	214	2054
	89.6%	10.4%	100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 32
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - All Cause Mortality (SEX).

Treatment Group Assignment=HIGH

The FREQ Procedure

Count / Overall % / Row %	0	1	Total
F	688 33.5% 89.7%	79 3.8% 10.3%	767 37.3%
M	1151 56.0% 89.3%	138 6.7% 10.7%	1289 62.7%
Total	1839 89.4%	217 10.6%	2056 100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 33
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - All Cause Mortality (SEX).

Treatment Group Assignment=LOW

The FREQ Procedure

Count / Overall % / Row %	0	1	Total
F	683 33.3% 89.8%	78 3.8% 10.2%	761 37.0%
M	1157 56.3% 89.5%	136 6.6% 10.5%	1293 63.0%
Total	1840 89.6%	214 10.4%	2054 100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 34
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - All Cause Mortality (RACE).

Treatment Group Assignment=HIGH

The FREQ Procedure

Count / Overall % / Row %	0	1	Total
Non-White	452 22.1% 89.0%	56 2.7% 11.0%	508 24.9%
White	1375 67.3% 89.6%	159 7.8% 10.4%	1534 75.1%
Total	1827 89.5%	215 10.5%	2042 100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 35
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - All Cause Mortality (RACE).

Treatment Group Assignment=LOW

The FREQ Procedure

Count / Overall % / Row %	0	1	Total
Non-White	439 21.5% 89.6%	51 2.5% 10.4%	490 24.0%
White	1388 68.0% 89.5%	162 7.9% 10.5%	1550 76.0%
Total	1827 89.6%	213 10.4%	2040 100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 36
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - All Cause Mortality (DM).

Treatment Group Assignment=HIGH

The FREQ Procedure

Count / Overall % / Row %	0	1	Total
N	1151 56.0% 92.7%	91 4.4% 7.3%	1242 60.4%
Y	687 33.4% 84.5%	126 6.1% 15.5%	813 39.6%
Total	1838 89.4%	217 10.6%	2055 100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 37
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - All Cause Mortality (DM).

Treatment Group Assignment=LOW

The FREQ Procedure

Count / Overall % / Row %	0	1	Total
N	1118 54.6% 93.3%	80 3.9% 6.7%	1198 58.5%
Y	716 35.0% 84.2%	134 6.5% 15.8%	850 41.5%
Total	1834 89.6%	214 10.4%	2048 100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 38
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - All Cause Mortality (HCY).

Treatment Group Assignment=HIGH

The FREQ Procedure

Count Overall % Row %	0	1	Total
<19.0 (75%tile)	1389 67.6% 90.3%	150 7.3% 9.7%	1539 74.9%
>=19.0 (75%tile)	450 21.9% 87.0%	67 3.3% 13.0%	517 25.1%
Total	1839 89.4%	217 10.6%	2056 100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 39
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - All Cause Mortality (HCY).

Treatment Group Assignment=LOW

The FREQ Procedure

Count Overall % Row %	0	1	Total
<19.0 (75%tile)	1405 68.4% 91.3%	134 6.5% 8.7%	1539 74.9%
>=19.0 (75%tile)	435 21.2% 84.5%	80 3.9% 15.5%	515 25.1%
Total	1840 89.6%	214 10.4%	2054 100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 40
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - Dialysis (AGE).

Treatment Group Assignment=HIGH

The FREQ Procedure

Count / Overall % / Row %	0	1	Total
<60	1442 70.1% 90.5%	152 7.4% 9.5%	1594 77.5%
60+	433 21.1% 93.7%	29 1.4% 6.3%	462 22.5%
Total	1875 91.2%	181 8.8%	2056 100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 41
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - Dialysis (AGE).

Treatment Group Assignment=LOW

The FREQ Procedure

Count / Overall % / Row %	0	1	Total
<60	1453 70.7% 91.0%	144 7.0% 9.0%	1597 77.8%
60+	439 21.4% 96.1%	18 0.9% 3.9%	457 22.2%
Total	1892 92.1%	162 7.9%	2054 100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 42
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - Dialysis (SEX).

Treatment Group Assignment=HIGH

The FREQ Procedure

Count / Overall % / Row %	0	1	Total
F	700 34.0% 91.3%	67 3.3% 8.7%	767 37.3%
M	1175 57.1% 91.2%	114 5.5% 8.8%	1289 62.7%
Total	1875 91.2%	181 8.8%	2056 100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 43
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - Dialysis (SEX).

Treatment Group Assignment=LOW

The FREQ Procedure

Count / Overall % / Row %	0	1	Total
F	707 34.4% 92.9%	54 2.6% 7.1%	761 37.0%
M	1185 57.7% 91.6%	108 5.3% 8.4%	1293 63.0%
Total	1892 92.1%	162 7.9%	2054 100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 44
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - Dialysis (RACE).

Treatment Group Assignment=HIGH

The FREQ Procedure

Count / Overall % / Row %	0	1	Total
Non-White	452	56	508
	22.1%	2.7%	24.9%
	89.0%	11.0%	
White	1411	123	1534
	69.1%	6.0%	75.1%
	92.0%	8.0%	
Total	1863	179	2042
	91.2%	8.8%	100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 45
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - Dialysis (RACE).

Treatment Group Assignment=LOW

The FREQ Procedure

Count / Overall % / Row %	0	1	Total
Non-White	441	49	490
	21.6%	2.4%	24.0%
	90.0%	10.0%	
White	1438	112	1550
	70.5%	5.5%	76.0%
	92.8%	7.2%	
Total	1879	161	2040
	92.1%	7.9%	100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 46
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - Dialysis (DM).

Treatment Group Assignment=HIGH

The FREQ Procedure

Count / Overall % / Row %	0	1	Total
N	1135 55.2% 91.4%	107 5.2% 8.6%	1242 60.4%
Y	740 36.0% 91.0%	73 3.6% 9.0%	813 39.6%
Total	1875 91.2%	180 8.8%	2055 100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 47
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - Dialysis (DM).

Treatment Group Assignment=LOW

The FREQ Procedure

Count / Overall % / Row %	0	1	Total
N	1117 54.5% 93.2%	81 4.0% 6.8%	1198 58.5%
Y	769 37.5% 90.5%	81 4.0% 9.5%	850 41.5%
Total	1886 92.1%	162 7.9%	2048 100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 48
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - Dialysis (HCY).

Treatment Group Assignment=HIGH

The FREQ Procedure

Count Overall % Row %	0	1	Total
<19.0 (75%tile)	1426 69.4% 92.7%	113 5.5% 7.3%	1539 74.9%
>=19.0 (75%tile)	449 21.8% 86.8%	68 3.3% 13.2%	517 25.1%
Total	1875 91.2%	181 8.8%	2056 100.0%

/prj/niddk/ims_analysis/FAVORIT/prog_initial_analysis/favorit_dsic2.sas
11:15 Monday, December 16, 2013 49
All tables limited to 4110 records with a value for TREATHL02 and Homocysteine Visit=0
Figure 3. Hazard ratios for treatment group comparisons from primary and secondary outcome subgroup analyses - Dialysis (HCY).

Treatment Group Assignment=LOW

The FREQ Procedure

Count Overall % Row %	0	1	Total
<19.0 (75%tile)	1437 70.0% 93.4%	102 5.0% 6.6%	1539 74.9%
>=19.0 (75%tile)	455 22.2% 88.3%	60 2.9% 11.7%	515 25.1%
Total	1892 92.1%	162 7.9%	2054 100.0%