Dataset Integrity Check for EDIC Year 12 Carotid IMT Data File

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**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**

The Epidemiology of Diabetes Interventions and Complications (EDIC) study was initiated as follow-up to examine the long-term effects of the original DCCT interventions on diabetic complications such as cardiovascular events and advanced retinal and renal disease. Over 90 percent of participants from the DDCT study were followed by the EDIC study. Similar to the DCCT study, glycosylated hemoglobin values, fasting lipid levels, serum creatinine values, and other risk factors for cardiovascular disease were measured at different intervals for participants. Cardiovascular complications were assessed with standardized means and classified by an independent committee. The EDIC study has found that intensive diabetes therapy reduced risk of cardiovascular disease in patients with type 1 diabetes and that the differences in outcomes between the intensive and conventional therapy groups persist after long-term study.

**3 Archived Datasets**

The SAS data file, as provided by the Data Coordinating Center (DCC), are located in the “\EDIC\EDIC Analysis Datasets\EDIC\_Year\_12\_Carotid\_IMT” folder in the data package. For this replication, variables were taken from the SAS file “nih\_usone1116.sas7bdat”.

**4 Statistical Methods**

Analyses were performed to duplicate results for the data published by the diabetes journals. To verify the integrity of the dataset, descriptive statistics were computed.

**5 Results**

For Table 1 in the publication [1], Table 1: Participant characteristics at DCCT baseline, DCCT closeout (EDIC baseline), and EDIC year 18, Table A lists the variables that can be used in the replication. Table B compares the results calculated from the archived data file to the results published in Table 1. The results of the replication are exactly match.

**6 Conclusions**

The NIDDK repository is confident that the EDIC data files to be distributed are an exact match to the manuscript data when available

**7 References**

[1] Progression of Carotid Artery Intima-Media Thickness During 12 Years in the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) Study

DIABETES, VOL. 60, FEBRUARY 2011diabetes.diabetesjournals.org **Table A:** Variables used to replicate Table 1: Clinical characteristics of 1116 EDIC participants with common carotid IMT measurements at years 1, 6, and 12 according to sex and original treatment assignment

|  |  |
| --- | --- |
| Table Variable | Variables Used in Replication from the Dataset(s) |
| Demographic year 6 Attained age (years) | A\_AGE06 |
| Attained type 1 duration (years) | A\_DRN06 |
| Smoking (%) | SMOKE06 |
| Body mass index 30 kg/m2 (%) | BMI30\_06 |
| Systolic blood pressure (mmHg) | SBP06 |
| Diastolic blood pressure (mmHg) | DBP06 |
| Hypertension (%) | HT06 |
| Total cholesterol (mg/dL) | TCHOL06 |
| HDL cholesterol (mg/dL) | HDL06 |
| LDL cholesterol (mg/dL) | LDL06 |
| Triglycerides (mg/dL) | TRIG06 |
| Hyperlipidemia (%) | HLIP06 |
| AER (mg/24h), year 5 or 6 | AER06 |
| Log (value [mg/24 h]) | LOGAER06 |
| 40 mg/24 h (%) | AER40\_06 |
| AER 40 or dialysis/transplant (ever) DCCT/EDIC to years 1-2 | A40Y01 |
| DCCT/EDIC to years 5-6 | A40Y06 |
| DCCT/EDIC to years 11-12 | A40Y12 |
| AER 300 or dialysis/transplant (ever) DCCT/EDIC to years 1-2 | A300Y01 |
| DCCT/EDIC to years 5-6 | A300Y06 |
| DCCT/EDIC to years 11-12 | A300Y12 |
| DCCT A1C | DCCT\_HBA |
| DCCT/EDIC to year 1 | WTMHBA01 |
| DCCT/EDIC to year 6 | WTMHBA06 |
| DCCT/EDIC to year 12 | WTMHBA12 |
| IMT year 1 | COMMNW01 |
| IMT year 6 | COMMNW06 |

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Character | Women Intensive [Manuscript] | Women Intensive [DSIC] | Women Intensive [Difference] | Women Conventional [Manuscript] | Women Conventional [DSIC] | Women Conventional [Difference] |
| Demographic year 6 Attained age (years) | 40+-7 | 40+-7 | 0+-0 | 39+-7 | 39+-7 | 0+-0 |
| Attained type 1 duration (years) | 19+-5 | 19+-5 | 0+-0 | 19+-5 | 19+-5 | 0+-0 |
| Smoking (%) | 16.5 | 17 | 0.5 | 15.3 | 15 | 0.3 |
| Body mass index 30 kg/m2 (%) | 24.3 | 24 | 0.3 | 15.6 | 16 | 0.4 |
| Systolic blood pressure (mmHg) | 118+-14 | 118+-14 | 0+-0 | 117+-14 | 117+-14 | 0+-0 |
| Diastolic blood pressure (mmHg) | 74+-9 | 74+-9 | 0+-0 | 73+-10 | 73+-10 | 0+-0 |
| Hypertension (%) | 24.9 | 25 | 0.1 | 28.6 | 29 | 0.4 |
| Total cholesterol (mg/dL) | 190+-33 | 190+-33 | 0+-0 | 187+-34 | 187+-34 | 0+-0 |
| HDL cholesterol (mg/dL) | 63+-16 | 63+-16 | 0+-0 | 62+-14 | 62+-14 | 0+-0 |
| LDL cholesterol (mg/dL) | 111+-30 | 111+-30 | 0+-0 | 109+-29 | 109+-29 | 0+-0 |
| Triglycerides (mg/dL) | 77+-42 | 77+-42 | 0+-0 | 76+-47 | 76+-47 | 0+-0 |
| Hyperlipidemia (%) | 30.3 | 30 | 0.3 | 26.3 | 26 | 0.3 |
| AER(mg/24h) year 5 and 6 (Median) | 10 | 10 | 0 | 10 | 10 | 0 |
| AER(mg/24h) year 5 and 6 (1st, 3rd quartile) | (6-17) | (6-17) | (0-0) | (6-21) | (6-21) | (0-0) |
| Log (value [mg/24 h]) | 2.3+-0.9 | 2+-1 | 0.3+-0.1 | 2.6+-1.3 | 3+-1 | 0.4+-0.3 |
| 40 mg/24 h (%) | 4.6 | 5 | 0.4 | 15.2 | 15 | 0.2 |
| AER 40 or dialysis/transplant (ever) DCCT/EDIC to years 1-2 | 27.7 | 28 | 0.3 | 30.8 | 31 | 0.2 |
| DCCT/EDIC to years 5-6 | 30.7 | 31 | 0.3 | 38 | 38 | 0 |
| DCCT/EDIC to years 11-12 | 37.1 | 37 | 0.1 | 44 | 44 | 0 |
| AER 300 or dialysis/transplant (ever) DCCT/EDIC to years 1-2 | 3 | 3 | 0 | 6 | 6 | 0 |
| DCCT/EDIC to years 5-6 | 3 | 3 | 0 | 8.3 | 8 | 0.3 |
| DCCT/EDIC to years 11-12 | 4.5 | 5 | 0.5 | 11.7 | 12 | 0.3 |
| DCCT A1C | 7.3+-0.8 | 7+-1 | 0.3+-0.2 | 9.1+-1.3 | 9+-1 | 0.1+-0.7 |
| DCCT/EDIC to year 1 | 7.3+-0.8 | 7+-1 | 0.3+-0.2 | 8.9+-1.2 | 9+-1 | 0.1+-0.2 |
| DCCT/EDIC to year 6 | 7.6+-0.9 | 8+-1 | 0.4+-0.1 | 8.6+-1.1 | 9+-1 | 0.4+-0.1 |
| DCCT/EDIC to year 12 | 7.7+-1.0 | 8+-1 | 0.3+-0 | 8.3+-1.0 | 8+-1 | 0.3+-0 |
| IMT year 1 Mean +- SD | 0.601+-0.080 | 1+-0 | 0.399+-0.08 | 0.582+-0.073 | 1+-0 | 0.418+-0.073 |
| IMT year 1 Median | 0.592 | 0.592 | 0 | 0.578 | 0.578 | 0 |
| IMT year 1 Range | (0.440-0.846) | (0.440-0.846) | (0.000-0.000) | (0.414-0.787) | (0.414-0.787) | (0.000-0.000) |
| IMT year 6 Mean +- SD | 0.613+-0.087 | 1+-0 | 0.387+-0.087 | 0.610+-0.096 | 1+-0 | 0.39+-0.096 |
| IMT year 6 Median | 0.602 | 0.602 | 0 | 0.6 | 0.6 | 0 |
| IMT year 6 Range | (0.411-0.928) | (0.411-0.928) | (0.000-0.000) | (0.417-1.121) | (0.417-1.121) | (0.000-0.000) |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Character | Men Intensive [Manuscript] | Men Intensive [DSIC] | Men  Intensive [Difference] | Men Conventional [Manuscript] | Men Conventional [DSIC] | Men Conventional [Difference] |
| Demographic year 6 Attained age (years) | 41+-7 | 41+-7 | 0+-0 | 41+-6 | 41+-6 | 0+-0 |
| Attained type 1 duration (years) | 19+-5 | 19+-5 | 0+-0 | 18+-5 | 18+-5 | 0+-0 |
| Smoking (%) | 18.6 | 19 | 0.4 | 13.3 | 13 | 0.3 |
| Body mass index 30 kg/m2 (%) | 21.8 | 22 | 0.2 | 18.6 | 19 | 0.4 |
| Systolic blood pressure (mmHg) | 122+-12 | 122+-12 | 0+-0 | 123+-13 | 123+-13 | 0+-0 |
| Diastolic blood pressure (mmHg) | 77+-9 | 77+-9 | 0+-0 | 77+-8 | 77+-8 | 0+-0 |
| Hypertension (%) | 30.5 | 31 | 0.5 | 35.1 | 35 | 0.1 |
| Total cholesterol (mg/dL) | 192+-38 | 192+-38 | 0+-0 | 187+-33 | 187+-33 | 0+-0 |
| HDL cholesterol (mg/dL) | 51+-13 | 51+-13 | 0+-0 | 51+-11 | 51+-11 | 0+-0 |
| LDL cholesterol (mg/dL) | 119+-30 | 119+-30 | 0+-0 | 117+-29 | 117+-29 | 0+-0 |
| Triglycerides (mg/dL) | 103+-73 | 103+-73 | 0+-0 | 98+-73 | 98+-73 | 0+-0 |
| Hyperlipidemia (%) | 36.6 | 37 | 0.4 | 35.8 | 36 | 0.2 |
| AER(mg/24h) year 5 and 6 (Median) | 10 | 10 | 0 | 12 | 12 | 0 |
| AER(mg/24h) year 5 and 6 (1st, 3rd quartile) | (7-16) | (7-16) | (0-0) | (7-29) | (7-29) | (0-0) |
| Log (value [mg/24 h]) | 2.5+-1.1 | 3+-1 | 0.5+-0.1 | 2.9+-1.4 | 3+-1 | 0.1+-0.4 |
| 40 mg/24 h (%) | 10.7 | 11 | 0.3 | 19.3 | 19 | 0.3 |
| AER 40 or dialysis/transplant (ever) DCCT/EDIC to years 1-2 | 17.6 | 18 | 0.4 | 26.1 | 26 | 0.1 |
| DCCT/EDIC to years 5-6 | 22.3 | 22 | 0.3 | 34.8 | 35 | 0.2 |
| DCCT/EDIC to years 11-12 | 30.4 | 30 | 0.4 | 40.4 | 40 | 0.4 |
| AER 300 or dialysis/transplant (ever) DCCT/EDIC to years 1-2 | 3 | 3 | 0 | 4.9 | 5 | 0.1 |
| DCCT/EDIC to years 5-6 | 3.7 | 4 | 0.3 | 10.1 | 10 | 0.1 |
| DCCT/EDIC to years 11-12 | 5.1 | 5 | 0.1 | 15.7 | 16 | 0.3 |
| DCCT A1C | 7.2+-0.8 | 7+-1 | 0.2+-0.2 | 8.9+-1.1 | 9+-1 | 0.1+-0.1 |
| DCCT/EDIC to year 1 | 7.3+-0.9 | 7+-1 | 0.3+-0.1 | 8.8+-1.0 | 9+-1 | 0.2+-0 |
| DCCT/EDIC to year 6 | 7.6+-1.0 | 8+-1 | 0.4+-0 | 8.6+-1.0 | 9+-1 | 0.4+-0 |
| DCCT/EDIC to year 12 | 7.7+-0.9 | 8+-1 | 0.3+-0.1 | 8.3+-1.0 | 8+-1 | 0.3+-0 |
| IMT year 1 Mean +- SD | 0.633+-0.088 | 1+-0 | 0.367+-0.088 | 0.637+-0.105 | 1+-0 | 0.363+-0.105 |
| IMT year 1 Median | 0.627 | 0.627 | 0 | 0.625 | 0.625 | 0 |
| IMT year 1 Range | (0.444-0.922) | (0.444-0.922) | (0.000-0.000) | (0.455-1.065) | (0.455-1.065) | (0.000-0.000) |
| IMT year 6 Mean +- SD | 0.647+-0.101 | 1+-0 | 0.353+-0.101 | 0.677+-0.141 | 1+-0 | 0.323+-0.141 |
| IMT year 6 Median | 0.636 | 0.636 | 0 | 0.646 | 0.646 | 0 |
| IMT year 6 Range | (0.440-1.133) | (0.440-1.133) | (0.000-0.000) | (0.425-1.772) | (0.425-1.772) | (0.000-0.000) |

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

\*\*\*Program:

\*\*\*Programmer: Jane

\*\*\*Date Created: 06/25/2015

\*\*\*Purpose:

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\*\*\*Source of Request:

\*\*\*Input Files:

\*\*\*

\*\*\*Output Files:

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\*\*\*History

\*\*\*Updated by:

\*\*\*Date Modified:

\*\*\*Updated Task:

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*;

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

title2 " ";

options nofmterr;

libname sasfile '/prj/niddk/ims\_analysis/DCCT\_EDIC/private\_orig\_data/EDIC\_06\_02\_2015/';

\*\*\* Data from the Primary outcome paper that was converted to .csv format so that the DSIC data could be easily compared;

FILENAME table1 '/prj/niddk/ims\_analysis/DCCT\_EDIC/private\_created\_data/Diabetes\_2011\_Polak\_table1.csv';

\*\*\* Output CSV files that will be converted to .xls before being added to the DSIC document;

FILENAME out\_t1 '/prj/niddk/ims\_analysis/DCCT\_EDIC/private\_created\_data/Diabetes\_2011\_Polak\_table1\_dsic.csv';

data nih\_usone1116;

set sasfile.nih\_usone1116;

proc sort data = nih\_usone1116;

by group;

%macro baseline\_freq2(dataset\_name,var\_name);

\*\*\* Creating a frequency table in the format of Table 1 in the primary outcome paper;

proc freq data = &dataset\_name ;

table (&var\_name.)\*group ;

where sex = 'F';

title3 "Frequency table of the &var\_name. variable in the analysis dataset";

\*\*\* Outputting the frequency data to work.&var\_name.\_cross using the ODS output;

ods output CrossTabFreqs = work.&var\_name.\_Fcross;

proc print data = &var\_name.\_Fcross;

data &var\_name.\_Fcross (keep =&var\_name GROUP colpercent table\_name ) ;

set &var\_name.\_Fcross;

if &var\_name =1 and GROUP ne '';

length table\_name $30.;

table\_name ="&var\_name";

proc print data = &var\_name.\_Fcross;

proc sort data = &var\_name.\_Fcross;

by table\_name group;

data &var\_name.\_Fcross;

set &var\_name.\_Fcross;

by table\_name ;

retain count 0;

if first.table\_name then count = 0;

count = count+1;

proc print data = &var\_name.\_Fcross;

data &var\_name.\_\_Fcross\_1(drop = &var\_name GROUP colpercent i count);

set &var\_name.\_Fcross;

by table\_name ;

array temp1(2) F\_stat1 F\_stat2 ;

retain F\_stat1 F\_stat2 ;

if first.table\_name then do i = 1 to 2;

temp1(i) = .;

end;

temp1(count) = colpercent;

if last.table\_name ;

proc print data = &var\_name.\_\_Fcross\_1;

proc freq data = &dataset\_name ;

table (&var\_name.)\*group ;

where sex = 'M';

title3 "Frequency table of the &var\_name. variable in the analysis dataset";

\*\*\* Outputting the frequency data to work.&var\_name.\_cross using the ODS output;

ods output CrossTabFreqs = work.&var\_name.\_Mcross;

proc print data = &var\_name.\_Mcross;

data &var\_name.\_Mcross (keep =&var\_name GROUP colpercent table\_name ) ;

set &var\_name.\_Mcross;

if &var\_name =1 and GROUP ne '';

length table\_name $30.;

table\_name ="&var\_name";

proc print data = &var\_name.\_Mcross;

proc sort data = &var\_name.\_Mcross;

by table\_name group;

data &var\_name.\_Mcross;

set &var\_name.\_Mcross;

by table\_name ;

retain count 0;

if first.table\_name then count = 0;

count = count+1;

proc print data = &var\_name.\_Mcross;

data &var\_name.\_\_Mcross\_1(drop = &var\_name GROUP colpercent i count);

set &var\_name.\_Mcross;

by table\_name ;

array temp1(2) M\_stat1 M\_stat2 ;

retain M\_stat1 M\_stat2 ;

if first.table\_name then do i = 1 to 2;

temp1(i) = .;

end;

temp1(count) = colpercent;

if last.table\_name ;

proc print data = &var\_name.\_\_Mcross\_1;

data &var\_name.\_cross\_1;

merge &var\_name.\_\_Mcross\_1 &var\_name.\_\_Fcross\_1;

by table\_name ;

proc print data = &var\_name.\_cross\_1;

%mend;

%macro baseline\_means(dataset\_name,var\_name);

\*\*\* Creating a frequency table in the format of Table 1 in the primary outcome paper;

proc means data = &dataset\_name mean Std ;

var &var\_name.;

by group;

where sex = 'M';

title3 "Frequency table of the &var\_name. variable in the analysis dataset";

\*\*\* Outputting the frequency data to work.&var\_name.\_cross using the ODS output;

ods output Summary = work.&var\_name.\_Mmean;

run;

proc print data = &var\_name.\_Mmean;

data &var\_name.\_Mmean;

set &var\_name.\_Mmean;

length table\_name $30.;

table\_name ="&var\_name";

proc print data = &var\_name.\_Mmean;

data &var\_name.\_Mmean\_1(keep = M\_stat1-M\_stat4 table\_name);

set &var\_name.\_Mmean;

by table\_name ;

array temp1(2) M\_stat1 M\_stat2 ;

array temp2(2) M\_stat3 M\_stat4;

retain M\_stat1-M\_stat4 ;

if first.table\_name then do i = 1 to 2;

temp1(i) = .;

temp2(i) = .;

end;

temp1(\_n\_) = &var\_name.\_Mean;

temp2(\_n\_) = &var\_name.\_StdDev;

if last.table\_name ;

proc print data = &var\_name.\_Mmean\_1;

proc means data = &dataset\_name mean Std ;

var &var\_name.;

by group;

where sex = 'F';

title3 "Frequency table of the &var\_name. variable in the analysis dataset";

\*\*\* Outputting the frequency data to work.&var\_name.\_cross using the ODS output;

ods output Summary = work.&var\_name.\_Fmean;

run;

proc print data = &var\_name.\_Fmean;

data &var\_name.\_Fmean;

set &var\_name.\_Fmean;

length table\_name $30.;

table\_name ="&var\_name";

proc print data = &var\_name.\_Fmean;

data &var\_name.\_Fmean\_1(keep = F\_stat1-F\_stat4 table\_name);

set &var\_name.\_Fmean;

by table\_name ;

array temp1(2) F\_stat1 F\_stat2 ;

array temp2(2) F\_stat3 F\_stat4;

retain F\_stat1-F\_stat4 ;

if first.table\_name then do i = 1 to 2;

temp1(i) = .;

temp2(i) = .;

end;

temp1(\_n\_) = &var\_name.\_Mean;

temp2(\_n\_) = &var\_name.\_StdDev;

if last.table\_name ;

proc print data = &var\_name.\_Fmean\_1;

data &var\_name.\_mean\_1;

merge &var\_name.\_Fmean\_1 &var\_name.\_Mmean\_1;

by table\_name ;

proc print data = &var\_name.\_mean\_1;

%mend;

%macro baseline\_range(dataset\_name,var\_name);

\*\*\* Creating a frequency table in the format of Table 1 in the primary outcome paper;

proc means data = &dataset\_name min max ;

var &var\_name.;

by group;

where sex = 'M';

title3 "Frequency table of the &var\_name. variable in the analysis dataset";

\*\*\* Outputting the frequency data to work.&var\_name.\_cross using the ODS output;

ods output Summary = work.&var\_name.\_Mrang;

run;

proc print data = &var\_name.\_Mrang;

data &var\_name.\_Mrang;

set &var\_name.\_Mrang;

length table\_name $30.;

table\_name ="&var\_name" || '\_range';

proc print data = &var\_name.\_Mrang;

data &var\_name.\_Mrang\_1(keep = M\_stat1-M\_stat4 table\_name);

set &var\_name.\_Mrang;

by table\_name ;

array temp1(2) M\_stat1 M\_stat2 ;

array temp2(2) M\_stat3 M\_stat4;

retain M\_stat1-M\_stat4 ;

if first.table\_name then do i = 1 to 2;

temp1(i) = .;

temp2(i) = .;

end;

temp1(\_n\_) = &var\_name.\_Min;

temp2(\_n\_) = &var\_name.\_Max;

if last.table\_name ;

proc print data = &var\_name.\_Mrang\_1;

proc means data = &dataset\_name min max ;

var &var\_name.;

by group;

where sex = 'F';

title3 "Frequency table of the &var\_name. variable in the analysis dataset";

\*\*\* Outputting the frequency data to work.&var\_name.\_cross using the ODS output;

ods output Summary = work.&var\_name.\_Frang;

run;

proc print data = &var\_name.\_Frang;

data &var\_name.\_Frang;

set &var\_name.\_Frang;

length table\_name $30.;

table\_name ="&var\_name" || '\_range';

proc print data = &var\_name.\_Frang;

data &var\_name.\_Frang\_1(keep = F\_stat1-F\_stat4 table\_name);

set &var\_name.\_Frang;

by table\_name ;

array temp1(2) F\_stat1 F\_stat2 ;

array temp2(2) F\_stat3 F\_stat4;

retain F\_stat1-F\_stat4 ;

if first.table\_name then do i = 1 to 2;

temp1(i) = .;

temp2(i) = .;

end;

temp1(\_n\_) = &var\_name.\_Min;

temp2(\_n\_) = &var\_name.\_Max;

if last.table\_name ;

proc print data = &var\_name.\_Frang\_1;

data &var\_name.\_rang\_1;

merge &var\_name.\_Frang\_1 &var\_name.\_Mrang\_1;

by table\_name ;

proc print data = &var\_name.\_rang\_1;

%mend;

%macro baseline\_quartile(dataset\_name,var\_name);

\*\*\* Creating a frequency table in the format of Table 1 in the primary outcome paper;

proc means data = &dataset\_name p25 p75 ;

var &var\_name.;

by group;

where sex = 'M';

title3 "Frequency table of the &var\_name. variable in the analysis dataset";

\*\*\* Outputting the frequency data to work.&var\_name.\_cross using the ODS output;

ods output Summary = work.&var\_name.\_Mquart;

run;

proc print data = &var\_name.\_Mquart;

data &var\_name.\_Mquart;

set &var\_name.\_Mquart;

length table\_name $30.;

table\_name ="&var\_name" || '\_quartile';

proc print data = &var\_name.\_Mquart;

data &var\_name.\_Mquart\_1(keep = M\_stat1-M\_stat4 table\_name);

set &var\_name.\_Mquart;

by table\_name ;

array temp1(2) M\_stat1 M\_stat2 ;

array temp2(2) M\_stat3 M\_stat4;

retain M\_stat1-M\_stat4 ;

if first.table\_name then do i = 1 to 2;

temp1(i) = .;

temp2(i) = .;

end;

temp1(\_n\_) = &var\_name.\_P25;

temp2(\_n\_) = &var\_name.\_P75;

if last.table\_name ;

proc print data = &var\_name.\_Mquart\_1;

proc means data = &dataset\_name p25 p75 ;

var &var\_name.;

by group;

where sex = 'F';

title3 "Frequency table of the &var\_name. variable in the analysis dataset";

\*\*\* Outputting the frequency data to work.&var\_name.\_cross using the ODS output;

ods output Summary = work.&var\_name.\_Fquart;

run;

proc print data = &var\_name.\_Fquart;

data &var\_name.\_Fquart;

set &var\_name.\_Fquart;

length table\_name $30.;

table\_name ="&var\_name" || '\_quartile';

proc print data = &var\_name.\_Fquart;

data &var\_name.\_Fquart\_1(keep = F\_stat1-F\_stat4 table\_name);

set &var\_name.\_Fquart;

by table\_name ;

array temp1(2) F\_stat1 F\_stat2 ;

array temp2(2) F\_stat3 F\_stat4;

retain F\_stat1-F\_stat4 ;

if first.table\_name then do i = 1 to 2;

temp1(i) = .;

temp2(i) = .;

end;

temp1(\_n\_) = &var\_name.\_P25;

temp2(\_n\_) = &var\_name.\_P75;

if last.table\_name ;

proc print data = &var\_name.\_Fquart\_1;

data &var\_name.\_quart\_1;

merge &var\_name.\_Fquart\_1 &var\_name.\_Mquart\_1;

by table\_name ;

proc print data = &var\_name.\_quart\_1;

%mend;

%macro baseline\_median(dataset\_name,var\_name);

\*\*\* Creating a frequency table in the format of Table 1 in the primary outcome paper;

proc means data = &dataset\_name median ;

var &var\_name.;

by group;

where sex = 'M';

title3 "Frequency table of the &var\_name. variable in the analysis dataset";

\*\*\* Outputting the frequency data to work.&var\_name.\_cross using the ODS output;

ods output Summary = work.&var\_name.\_Mmedian;

run;

proc print data = &var\_name.\_Mmedian;

data &var\_name.\_Mmedian;

set &var\_name.\_Mmedian;

length table\_name $30.;

table\_name ="&var\_name" || '\_median';

proc print data = &var\_name.\_Mmedian;

data &var\_name.\_Mmedian\_1(keep = M\_stat1-M\_stat2 table\_name);

set &var\_name.\_Mmedian;

by table\_name ;

array temp1(2) M\_stat1 M\_stat2 ;

retain M\_stat1-M\_stat2 ;

if first.table\_name then do i = 1 to 2;

temp1(i) = .;

end;

temp1(\_n\_) = &var\_name.\_median;

if last.table\_name ;

proc print data = &var\_name.\_Mmedian\_1;

proc means data = &dataset\_name median ;

var &var\_name.;

by group;

where sex = 'F';

title3 "Frequency table of the &var\_name. variable in the analysis dataset";

\*\*\* Outputting the frequency data to work.&var\_name.\_cross using the ODS output;

ods output Summary = work.&var\_name.\_Fmedian;

run;

proc print data = &var\_name.\_Fmedian;

data &var\_name.\_Fmedian;

set &var\_name.\_Fmedian;

length table\_name $30.;

table\_name ="&var\_name" || '\_median';

proc print data = &var\_name.\_Fmedian;

data &var\_name.\_Fmedian\_1(keep = F\_stat1-F\_stat2 table\_name);

set &var\_name.\_Fmedian;

by table\_name ;

array temp1(2) F\_stat1 F\_stat2 ;

retain F\_stat1-F\_stat2 ;

if first.table\_name then do i = 1 to 2;

temp1(i) = .;

end;

temp1(\_n\_) = &var\_name.\_median;

if last.table\_name ;

proc print data = &var\_name.\_Fmedian\_1;

data &var\_name.\_median\_1;

merge &var\_name.\_Fmedian\_1 &var\_name.\_Mmedian\_1;

by table\_name ;

proc print data = &var\_name.\_median\_1;

%mend;

%baseline\_quartile(nih\_usone1116, AER06 );

%baseline\_median(nih\_usone1116, AER06 );

%baseline\_median(nih\_usone1116, COMMNW01 );

%baseline\_median(nih\_usone1116, COMMNW06 );

%baseline\_range(nih\_usone1116, COMMNW01 );

%baseline\_range(nih\_usone1116, COMMNW06 );

%baseline\_means(nih\_usone1116, A\_AGE06 );

%baseline\_means(nih\_usone1116, A\_DRN06 );

%baseline\_means(nih\_usone1116, SBP06 );

%baseline\_means(nih\_usone1116, DBP06 );

%baseline\_means(nih\_usone1116, TCHOL06 );

%baseline\_means(nih\_usone1116, HDL06 );

%baseline\_means(nih\_usone1116, LDL06 );

%baseline\_means(nih\_usone1116, TRIG06 );

%baseline\_means(nih\_usone1116, AER06 );

%baseline\_means(nih\_usone1116, LOGAER06 );

%baseline\_means(nih\_usone1116, DCCT\_HBA );

%baseline\_means(nih\_usone1116, WTMHBA01 );

%baseline\_means(nih\_usone1116, WTMHBA06 );

%baseline\_means(nih\_usone1116, WTMHBA12 );

%baseline\_means(nih\_usone1116, COMMNW01 );

%baseline\_means(nih\_usone1116, COMMNW06 );

%baseline\_freq2(nih\_usone1116,SMOKE06 );

%baseline\_freq2(nih\_usone1116,BMI30\_06 );

%baseline\_freq2(nih\_usone1116,HT06 );

%baseline\_freq2(nih\_usone1116,HLIP06 );

%baseline\_freq2(nih\_usone1116,AER40\_06 );

%baseline\_freq2(nih\_usone1116,A40Y01 );

%baseline\_freq2(nih\_usone1116,A40Y06 );

%baseline\_freq2(nih\_usone1116,A40Y12 );

%baseline\_freq2(nih\_usone1116,A300Y01 );

%baseline\_freq2(nih\_usone1116,A300Y06 );

%baseline\_freq2(nih\_usone1116,A300Y12 );

data table1\_compare;

set

A\_AGE06\_mean\_1

A\_DRN06\_mean\_1

SMOKE06\_cross\_1

BMI30\_06\_cross\_1

SBP06\_mean\_1

DBP06\_mean\_1

HT06\_cross\_1

TCHOL06\_mean\_1

HDL06\_mean\_1

LDL06\_mean\_1

TRIG06\_mean\_1

HLIP06\_cross\_1

AER06\_MEDIAN\_1

AER06\_QUART\_1

AER40\_06\_cross\_1

A40Y01\_cross\_1

A40Y06\_cross\_1

A40Y12\_cross\_1

LOGAER06\_mean\_1

A300Y01\_cross\_1

A300Y06\_cross\_1

A300Y12\_cross\_1

DCCT\_HBA\_mean\_1

WTMHBA01\_mean\_1

WTMHBA06\_mean\_1

WTMHBA12\_mean\_1

COMMNW01\_mean\_1

COMMNW01\_MEDIAN\_1 COMMNW01\_RANG\_1 COMMNW06\_mean\_1 COMMNW06\_MEDIAN\_1 COMMNW06\_RANG\_1

;

proc print data = table1\_compare ;

\*\*\* Importing the Table 1 Data taken from the primary outcome paper;

data table1\_data;

infile table1 delimiter = ',' MISSOVER DSD firstobs=1 ls=1080;

length character $100. table\_name $ 30. Fchar\_stat1\_ Fchar\_stat2\_ Mchar\_stat1\_ Mchar\_stat2\_ $ 20. ;

input character $ table\_name $ Fchar\_stat1\_ $ Fchar\_stat2\_ $ Mchar\_stat1\_ $ Mchar\_stat2\_ $ p $

;

data table1\_data;

set table1\_data;

Fchar\_stat1\_ = compress(Fchar\_stat1\_);

Fchar\_stat2\_ = compress(Fchar\_stat2\_);

Mchar\_stat1\_ = compress(Mchar\_stat1\_);

Mchar\_stat2\_ = compress(Mchar\_stat2\_);

ordernum = \_n\_;

if index(Fchar\_stat1\_, '(') > 0 then do;

f\_stat1\_ = input(substr(Fchar\_stat1\_,2,index(Fchar\_stat1\_,'-')-2),8.);

f\_stat3\_ = input(substr(Fchar\_stat1\_,index(Fchar\_stat1\_,'-')+1, length(Fchar\_stat1\_)-index(Fchar\_stat1\_,'-')-1),8.);

f\_stat2\_ = input(substr(Fchar\_stat2\_,2,index(Fchar\_stat2\_,'-')-2),8.);

f\_stat4\_ = input(substr(Fchar\_stat2\_,index(Fchar\_stat2\_,'-')+1, length(Fchar\_stat2\_)-index(Fchar\_stat2\_,'-')-1),8.);

end;

else if index(Fchar\_stat1\_, '+') > 0 then do;

f\_stat1\_ = input(substr(Fchar\_stat1\_,1,index(Fchar\_stat1\_,'-')-2),8.);

f\_stat3\_ = input(substr(Fchar\_stat1\_,index(Fchar\_stat1\_,'-')+1, length(Fchar\_stat1\_)-index(Fchar\_stat1\_,'-')),8.);

f\_stat2\_ = input(substr(Fchar\_stat2\_,1,index(Fchar\_stat2\_,'-')-2),8.);

f\_stat4\_ = input(substr(Fchar\_stat2\_,index(Fchar\_stat2\_,'-')+1, length(Fchar\_stat2\_)-index(Fchar\_stat2\_,'-')),8.);

end;

else do;

f\_stat1\_ = input (Fchar\_stat1\_,8.);

f\_stat2\_ = input (Fchar\_stat2\_,8.);

end;

if index(Mchar\_stat1\_, '(') > 0 then do;

m\_stat1\_ = input(substr(Mchar\_stat1\_,2,index(Mchar\_stat1\_,'-')-2),8.);

m\_stat3\_ = input(substr(Mchar\_stat1\_,index(Mchar\_stat1\_,'-')+1, length(Mchar\_stat1\_)-index(Mchar\_stat1\_,'-')-1),8.);

m\_stat2\_ = input(substr(Mchar\_stat2\_,2,index(Mchar\_stat2\_,'-')-2),8.);

m\_stat4\_ = input(substr(Mchar\_stat2\_,index(Mchar\_stat2\_,'-')+1, length(Mchar\_stat2\_)-index(Mchar\_stat2\_,'-')-1),8.);

end;

else if index(Mchar\_stat1\_, '+') > 0 then do;

m\_stat1\_ = input(substr(Mchar\_stat1\_,1,index(Mchar\_stat1\_,'-')-2),8.);

m\_stat3\_ = input(substr(Mchar\_stat1\_,index(Mchar\_stat1\_,'-')+1, length(Mchar\_stat1\_)-index(Mchar\_stat1\_,'-')),8.);

m\_stat2\_ = input(substr(Mchar\_stat2\_,1,index(Mchar\_stat2\_,'-')-2),8.);

m\_stat4\_ = input(substr(Mchar\_stat2\_,index(Mchar\_stat2\_,'-')+1, length(Mchar\_stat2\_)-index(Mchar\_stat2\_,'-')),8.);

end;

else do;

m\_stat1\_ = input (Mchar\_stat1\_,8.);

m\_stat2\_ = input (Mchar\_stat2\_,8.);

end;

proc print data = table1\_data;

proc sort data = table1\_data;

by table\_name ;

proc sort data = table1\_compare;

by table\_name ;

data table1\_combine;

merge table1\_data (in = in2) table1\_compare (in = in1);

by table\_name;

if in1 and in2;

data table1\_combine;

set table1\_combine;

if table\_name in ('A\_AGE06' 'A\_DRN06' 'SBP06' 'DBP06' 'TCHOL06' 'HDL06' 'LDL06' 'TRIG06') then do;

Fdiff\_stat1 = compress(put(round(F\_stat1\_,1)-round(F\_stat1,1),8.) || '+-' || put(round(F\_stat3\_,1)-round(F\_stat3,1),8.));

Fdiff\_stat2 = compress(put(round(F\_stat2\_,1)-round(F\_stat2,1),8.) || '+-' || put(round(F\_stat4\_,1)-round(F\_stat4,1),8.));

Mdiff\_stat1 = compress(put(round(M\_stat1\_,1)-round(M\_stat1,1),8.) || '+-' || put(round(M\_stat3\_,1)-round(M\_stat3,1),8.));

Mdiff\_stat2 = compress(put(round(M\_stat2\_,1)-round(M\_stat2,1),8.) || '+-' || put(round(M\_stat4\_,1)-round(M\_stat4,1),8.));

Fchar\_stat1 = compress(put(round(F\_stat1,1),8.) || '+-' || put(round(F\_stat3,1),8.));

Fchar\_stat2 = compress(put(round(F\_stat2,1),8.) || '+-' || put(round(F\_stat4,1),8.));

Mchar\_stat1 = compress(put(round(M\_stat1,1),8.) || '+-' || put(round(M\_stat3,1),8.));

Mchar\_stat2 = compress(put(round(M\_stat2,1),8.) || '+-' || put(round(M\_stat4,1),8.));

end;

else if table\_name in ('SMOKE06' 'BMI30\_06' 'HT06' 'HLIP06' 'AER06\_median' 'AER40\_06' 'A40Y01' 'A40Y06' 'A40Y12' 'A300Y01' 'A300Y06' 'A300Y12') then do;

Fdiff\_stat1 = compress(put(round(F\_stat1\_,.1)-round(F\_stat1,.1),8.));

Fdiff\_stat2 = compress(put(round(F\_stat2\_,.1)-round(F\_stat2,.1),8.));

Mdiff\_stat1 = compress(put(round(M\_stat1\_,.1)-round(M\_stat1,.1),8.));

Mdiff\_stat2 = compress(put(round(M\_stat2\_,.1)-round(M\_stat2,.1),8.));

Fchar\_stat1 = compress(put(round(F\_stat1,.1),8.));

Fchar\_stat2 = compress(put(round(F\_stat2,.1),8.));

Mchar\_stat1 = compress(put(round(M\_stat1,.1),8.));

Mchar\_stat2 = compress(put(round(M\_stat2,.1),8.));

end;

else if table\_name in ('LOGAER06' 'DCCT\_HBA' 'WTMHBA01' 'WTMHBA06' 'WTMHBA12') then do;

Fdiff\_stat1 = compress(put(round(F\_stat1\_,.1)-round(F\_stat1,.1),8.) || '+-' || put(round(F\_stat3\_,.1)-round(F\_stat3,.1),8.));

Fdiff\_stat2 = compress(put(round(F\_stat2\_,.1)-round(F\_stat2,.1),8.) || '+-' || put(round(F\_stat4\_,.1)-round(F\_stat4,.1),8.));

Mdiff\_stat1 = compress(put(round(M\_stat1\_,.1)-round(M\_stat1,.1),8.) || '+-' || put(round(M\_stat3\_,.1)-round(M\_stat3,.1),8.));

Mdiff\_stat2 = compress(put(round(M\_stat2\_,.1)-round(M\_stat2,.1),8.) || '+-' || put(round(M\_stat4\_,.1)-round(M\_stat4,.1),8.));

Fchar\_stat1 = compress(put(round(F\_stat1,.1),8.) || '+-' || put(round(F\_stat3,.1),8.));

Fchar\_stat2 = compress(put(round(F\_stat2,.1),8.) || '+-' || put(round(F\_stat4,.1),8.));

Mchar\_stat1 = compress(put(round(M\_stat1,.1),8.) || '+-' || put(round(M\_stat3,.1),8.));

Mchar\_stat2 = compress(put(round(M\_stat2,.1),8.) || '+-' || put(round(M\_stat4,.1),8.));

end;

else if table\_name in ('COMMNW01' 'COMMNW06') then do;

Fdiff\_stat1 = compress(put(round(F\_stat1\_,.001)-round(F\_stat1,.001),8.) || '+-' || put(round(F\_stat3\_,.001)-round(F\_stat3,.001),8.));

Fdiff\_stat2 = compress(put(round(F\_stat2\_,.001)-round(F\_stat2,.001),8.) || '+-' || put(round(F\_stat4\_,.001)-round(F\_stat4,.001),8.));

Mdiff\_stat1 = compress(put(round(M\_stat1\_,.001)-round(M\_stat1,.001),8.) || '+-' || put(round(M\_stat3\_,.001)-round(M\_stat3,.001),8.));

Mdiff\_stat2 = compress(put(round(M\_stat2\_,.001)-round(M\_stat2,.001),8.) || '+-' || put(round(M\_stat4\_,.001)-round(M\_stat4,.001),8.));

Fchar\_stat1 = compress(put(round(F\_stat1,.001),8.) || '+-' || put(round(F\_stat3,.001),8.));

Fchar\_stat2 = compress(put(round(F\_stat2,.001),8.) || '+-' || put(round(F\_stat4,.001),8.));

Mchar\_stat1 = compress(put(round(M\_stat1,.001),8.) || '+-' || put(round(M\_stat3,.001),8.));

Mchar\_stat2 = compress(put(round(M\_stat2,.001),8.) || '+-' || put(round(M\_stat4,.001),8.));

end;

else if table\_name in ('COMMNW01\_range ' 'COMMNW06\_range') then do;

Fdiff\_stat1 =compress( '(' || put(round(F\_stat1\_,.001)-round(F\_stat1,.001),8.3) || '-' || put(round(F\_stat3\_,.001)-round(F\_stat3,.001),8.3) || ')');

Fdiff\_stat2 =compress( '(' || put(round(F\_stat2\_,.001)-round(F\_stat2,.001),8.3) || '-' || put(round(F\_stat4\_,.001)-round(F\_stat4,.001),8.3) || ')');

Mdiff\_stat1 =compress( '(' || put(round(M\_stat1\_,.001)-round(M\_stat1,.001),8.3) || '-' || put(round(M\_stat3\_,.001)-round(M\_stat3,.001),8.3) || ')');

Mdiff\_stat2 =compress( '(' || put(round(M\_stat2\_,.001)-round(M\_stat2,.001),8.3) || '-' || put(round(M\_stat4\_,.001)-round(M\_stat4,.001),8.3) || ')');

Fchar\_stat1 =compress( '(' || put(round(F\_stat1,.001),8.3) || '-' || put(round(F\_stat3,.001),8.3) || ')');

Fchar\_stat2 =compress( '(' || put(round(F\_stat2,.001),8.3) || '-' || put(round(F\_stat4,.001),8.3) || ')');

Mchar\_stat1 =compress( '(' || put(round(M\_stat1,.001),8.3) || '-' || put(round(M\_stat3,.001),8.3) || ')');

Mchar\_stat2 =compress( '(' || put(round(M\_stat2,.001),8.3) || '-' || put(round(M\_stat4,.001),8.3) || ')');

end;

else if table\_name in ('COMMNW01\_median' 'COMMNW06\_median') then do;

Fdiff\_stat1 = compress(put(round(F\_stat1\_,.001)-round(F\_stat1,.001),8.3));

Fdiff\_stat2 = compress(put(round(F\_stat2\_,.001)-round(F\_stat2,.001),8.3));

Mdiff\_stat1 = compress(put(round(M\_stat1\_,.001)-round(M\_stat1,.001),8.3));

Mdiff\_stat2 = compress(put(round(M\_stat2\_,.001)-round(M\_stat2,.001),8.3));

Fchar\_stat1 = compress(put(round(F\_stat1,.001),8.3));

Fchar\_stat2 = compress(put(round(F\_stat2,.001),8.3));

Mchar\_stat1 = compress(put(round(M\_stat1,.001),8.3));

Mchar\_stat2 = compress(put(round(M\_stat2,.001),8.3));

end;

else if table\_name in ('AER06\_quartile') then do;

Fdiff\_stat1 = compress('(' || put(round(F\_stat1\_,1)-round(F\_stat1,1),8.) || '-' || put(round(F\_stat3\_,1)-round(F\_stat3,1),8.) || ')');

Fdiff\_stat2 = compress('(' || put(round(F\_stat2\_,1)-round(F\_stat2,1),8.) || '-' || put(round(F\_stat4\_,1)-round(F\_stat4,1),8.) || ')');

Mdiff\_stat1 = compress('(' || put(round(M\_stat1\_,1)-round(M\_stat1,1),8.) || '-' || put(round(M\_stat3\_,1)-round(M\_stat3,1),8.) || ')');

Mdiff\_stat2 = compress('(' || put(round(M\_stat2\_,1)-round(M\_stat2,1),8.) || '-' || put(round(M\_stat4\_,1)-round(M\_stat4,1),8.) || ')');

Fchar\_stat1 = compress('(' || put(round(F\_stat1,1),8.) || '-' || put(round(F\_stat3,1),8.) || ')');

Fchar\_stat2 = compress('(' || put(round(F\_stat2,1),8.) || '-' || put(round(F\_stat4,1),8.) || ')');

Mchar\_stat1 = compress('(' || put(round(M\_stat1,1),8.) || '-' || put(round(M\_stat3,1),8.) || ')');

Mchar\_stat2 = compress('(' || put(round(M\_stat2,1),8.) || '-' || put(round(M\_stat4,1),8.) || ')');

end;

label

character = "character"

Fchar\_stat1\_ = "women intensive [Manuscript]"

Fchar\_stat1 = "women intensive [DSIC] "

Fdiff\_stat1 = "women intensive [Difference]"

Fchar\_stat2\_ = "women conventional [Manuscript]"

Fchar\_stat2 = "women conventional [DSIC] "

Fdiff\_stat2 = "women conventional [Difference]"

Mchar\_stat1\_ = "Men intensive [Manuscript]"

Mchar\_stat1 = "Men intensive [DSIC] "

Mdiff\_stat1 = "Men intensive [Difference]"

Mchar\_stat2\_ = "Men conventional [Manuscript]"

Mchar\_stat2 = "Men conventional [DSIC] "

Mdiff\_stat2 = "Men conventional [Difference]"

;

proc sort data = table1\_combine;

by ordernum;

\*\*\* Outputting the data to a csv format to be added to the DSIC;

ods csv file = out\_t1;

run;

proc print data = table1\_combine NOOBS label ;

var

character table\_name

Fchar\_stat1\_

Fchar\_stat1

Fdiff\_stat1

Fchar\_stat2\_

Fchar\_stat2

Fdiff\_stat2

Mchar\_stat1\_

Mchar\_stat1

Mdiff\_stat1

Mchar\_stat2\_

Mchar\_stat2

Mdiff\_stat2

;

title "DSIC Check of Table 1 ";

run;