**FDA JUMPSTART SCRIPTS**

**TESTING USING FDA DATA**

**PROGRAM NAME**: ae\_oncology\_v1.sas (AE Toxicity)

**TESTING AUTHORS**: Rebeka Revis

**SAS VERSION**: 9.2

**DESCRIPTION**: The program was tested on a local drive in Windows 7 in order to produce adverse events summaries for oncology data using FDA-provided de-identified data.

**TESTING STEPS**

1. All the necessary files were stored on a local computer drive.
2. The FDA-provided data did not have the standard toxicity grade. This variable was derived.

If AESER=”MILD” then AETOXGR=1;

Else if AESER=”MODERATE” then AETOXGR=2;

Else if AESER=”SEVERE” then AETOXGR=4;

1. Create a file containing the MedDRA hierarchy for dictionary version 14.1.
2. CHANGES MADE TO THE SCRIPT TO MAKE IT RUN: the following parameters were defined in order to point to the right locations on the local drive:
   * Studypath: location of the drug study datasets.
   * Utilpath: location of external SAS programs.
   * Templatepath: filename of the template.
   * Outpath: location of the output.
   * Parameter values were hard-coded in the original version of the macro %PARAMS. Initialized these variables in the macro call.

Changes needed to supporting macros.

* + Sl\_gs\_output.sas (in the “ZZ\_Utilities” folder)
    - Uncomment line 525 and comment out line 526 to run on local drive

1. Run the program.
2. No warnings found in the log.
3. Errors found in the log (did not seem to affect the output):

NOTE: There were 107 observations read from the data set SASHELP.VMACRO.

WHERE (scope='GLOBAL') and (name not = 'RUN\_LOCATION');

NOTE: The data set WORK.MACROVAR has 107 observations and 2 variables.

NOTE: DATA statement used (Total process time):

real time 0.01 seconds

cpu time 0.01 seconds

ERROR: Attempt to delete automatic macro variable SYS\_SQL\_IP\_ALL.

ERROR: Attempt to delete automatic macro variable SYS\_SQL\_IP\_STMT.

NOTE: DATA statement used (Total process time):

real time 0.00 seconds

cpu time 0.00 seconds

NOTE: The SAS System stopped processing this step because of errors.

NOTE: There were 107 observations read from the data set WORK.MACROVAR

1. Check that the output files was created (AE Toxicity Analysis.xls).

**ADDITIONAL WORK PERFORMED**

In ae\_oncology\_v1.sas, the macro params did not include parameter values. The user needed to manually set macro variable values within %params. This has been updated so that parameters are set in the macro call statement.

Created macr variables for %PARAMS instead of relying on hard-coding:

%params(in\_panel\_title=AE Toxicity,

in\_panel\_desc=,

in\_saspath=H:\GPS\Phuse\programs\SAS Include Programs,

in\_utilpath=H:\GPS\Phuse\programs\ZZ\_Utilities,

in\_outpath=H:\GPS\Phuse\programs\tfl\_output,

in\_oncaeout=AE Toxicity Analysis.xls,

in\_errout=AE Toxicity Error Summary.xls,

in\_studypath=H:\GPS\Phuse\programs\AE\_Toxicity\CDISC Dat,

in\_ndabla=,

in\_studyid=DeID,

in\_meddrapath=H:\GPS\Phuse\programs\AE\_Toxicity,

in\_ver=14.1,

in\_study\_lag=30,

in\_toxgr\_grp5\_sw=1,

in\_exp=1,

in\_ctl=2,

in\_cmpgr=all,

in\_cmptrm = %str(soc\_name,pt\_name),

in\_cmpsort = rr,

in\_cc=0.5);

Below are descriptions of the variables based on the comments from within the macro params.

in\_panel\_title: Output panel title

in\_panel\_desc: Output panel description

in\_saspath: location of panel external SAS programs

in\_utilpath: location of utility external SAS programs

in\_outpath: location of the output

in\_oncaeout: Output Excel file name

in\_errout: Output Excel error summary file name

in\_studypath: Location of the drug study datasets

in\_ndabla: NDA/BLA

in\_studyid: Study ID

in\_meddrapath: Path to MedDRA hierachy

in\_ver: MedDRA dictionary version

in\_study\_lag: study lag in days - determines window in days following the end of a study in which AEs should be included in the analysis

in\_toxgr\_grp5\_sw: Toxicity grade 5 grouping switch to group 5 with 3 and 4 in the oncology panel

in\_exp: Experiment arm defined by arm number from all\_arm

in\_ctl: Control arm defined by arm number from all\_arm

in\_cmpgr: grades to use in comparison in the two-term analysis valid values: all, 5, 34, 345

in\_cmptrm: Comparison terms

in\_cmpsort: Sort variable

in\_cc: continuity correction method arm adds the reciprocal of the opposite arm otherwise any number is added as a constant

**SUGGESTION**

Each of the Excel templates gives a page that allows sub-setting or grouping by a variable. The documentation is not clear on how to do subgroup analyses.

Remove the hard-coding from %PARAMS and initialize each variable in the macro call.

Better descriptions of the variables in %PARAMS would help. For example, are there any values a variable cannot be (i.e, restrictions on &cc)? Are there restrictions on variable formatting?