**FDA JUMPSTART SCRIPTS**

**TESTING USING FDA DATA**

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

**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 using FDA-provided de-identified data.

**TESTING STEPS**

1. All the necessary files were stored on a local computer drive.
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.

* + ae\_rror.sas (in the “SAS Include Macro” folder)
    - Uncomment line 806 and comment out line 807 to run on local drive.
    - Uncomment line 846 and comment out line 847 to run on local drive.
  + 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. Check that LOG file is free of ERRORS and WARNINGS
3. Check that three output files were created (AE Severtiy.xls, Adverse Events Relative Risk Analysis.xls, and Adverse Events Odds Ratio Analysis.xls).

**ADDITIONAL WORK PERFORMED**

In ae\_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 Severity,

in\_panel\_desc = AE Severity Panel,

in\_saspath = ,

in\_utilpath = ,

in\_outpath = ,

in\_studypath = ,

in\_ndabla = ,

in\_studyid = ,

in\_templatepath = ,

in\_studylag = 120,

in\_cc = 0)

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\_studypath: Location of the drug study datasets

in\_ndabla: NDA/BLA

in\_studyid: Study ID

in\_templatepath: location of the Excel templates

in\_studylag: Study lag in days. Determines the window in days following the end of a study in which adverse events should be included in the analysis.

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 in 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?